The Thesis committee for John Thomas Montgomery

Certifies that this is the approved version of the following thesis:

Investigation and Design of an Actively Actuated

Lower-Limb Prosthetic Socket

APPROVED BY
SUPERVISING COMMITTEE:

Supervisor: ______________________________

Richard H. Crawford

____

Ronald E. Barr

Investigation and Design of an Actively Actuated Lower-Limb Prosthetic Socket

by

John Thomas Montgomery, BSME

Thesis

Presented to the Faculty of the Graduate School

of the University of Texas at Austin

in Partial Fulfillment

of the Requirements

for the Degree of

Master of Science in Engineering

The University of Texas at Austin

December 2009

Dedication

For Ruth Erin

Acknowledgements

The author wishes to express his deepest thanks to his advisor, Dr. Richard H. Crawford, for providing this research opportunity and for guidance, encouragement and support throughout the completion of this work.

The author also wishes to thank his research partner, Meagan Vaughan, for providing introductions to the area of research, and support in understanding and controlling the Selective Laser Sintering. Similarly, the author is appreciative of the help of Mitchell George, an undergraduate student, for assisting with setup and break out of the builds and for testing support.

Other graduate students who were helpful throughout this work include Timothy Silverman and Allison Hall. Mark Phillips, the technician working with the SLS machine, was a helpful resource, as were Kent Firestone of SolidConcepts and David Leigh of Harvest Technologies for their experience and knowledge of SLS machines and processes.

The author is indebted to many others for their support and encouragement. He thanks his parents for their support throughout his education and his fiancée for her time spent editing this thesis and for the inspiration to complete it.

JOHN THOMAS MONTGOMERY

The University of Texas at Austin

December 2009

Investigation and Design of an Actively Actuated Lower-Limb Prosthetic Socket

by

John Thomas Montgomery, MSE

The University of Texas at Austin, 2009

SUPERVISOR: Richard H. Crawford

A prosthetic socket worn by an amputee must serve a wide variety of functions, from stationary support to the transfer of forces necessary to move. Fit and comfort are important factors in determining the therapeutic effectiveness of a socket. A socket that does not fit the subject well will cause movement problems and potentially long-term health issues. Because a subject's residual limb changes volume throughout the day, it is desirable that the socket adapt to accommodate volume changes to maintain fit and comfort. This thesis presents research to manufacture adaptive sockets using selective laser sintering (SLS). This additive manufacturing process allows freedom to design a socket that has both compliant areas that can adapt to changes to the residual limb, as well as rigid regions to provide necessary support for the limb. A variety of concepts are discussed that are intended for manufacture by SLS, and that feature flexible inner membranes in various configurations. For each concept the membrane will be inflated or deflated to match the limb’s change in volume and the thesis also presents a study to determine SLS machine parameters for optimal build results. A series of experiments was created to understand the ability of SLS manufactured plastics to be inflated and the possible performance.

Table of Contents

LIST OF TABLES……………………………………………………………..x
LIST OF FIGURES…………………………………………………………..xi

CHAPTER 1: INTRODUCTION……………………………………………………1
1.1. Introduction to Area of Research……………………………………………1
1.2. Focus of Research……………………………………………………………3
1.3. Objective………………………………………………………………………4
1.4. Thesis Layout…………………………………………………………………4

CHAPTER 2: BACKGROUND……………………………………………………8
2.1. Prosthetic Socket Overview…………………………………………………8
2.2. Customer Need………………………………………………………………9
2.3. State of the Art………………………………………………………………11
2.4. Selective Laser Sintering……………………………………………………14
2.5. Previous SLS Work on Prosthetic Sockets…………………………………16
2.6. Summary………………………………………………………………………19

CHAPTER 3: DESIGN OF AN ACTIVELY ACTUATED PROSTHETIC SOCKET……………………………………………………………21
3.1. Introduction……………………………………………………………………21
3.2. Concept Generation & Results………………………………………………22
3.3. Designing Functional Mechanical Parts with SLS…………………………25
3.4. Design of Deflection Test Pieces……………………………………………26
3.4.1. Design of Flat Deflection Test Piece……………………………………27
3.4.1.1. Theoretical Evaluation…………………………………………………31
3.4.1.2. Closed Form Equation for Plate Deflection…………………………31
3.4.1.3. Finite Element Analysis of Flat Plate Deflection……………………36
3.4.2. Design of Curved Deflection Test Piece…………………………………40
3.4.2.1. Finite Element Analysis of Curved Test Specimen……………………42
3.5. Summary………………………………………………………………………43

CHAPTER 4: EXPERIMENTAL VERIFICATION OF AN ACTIVELY ACTUATED PROSTHETIC SOCKET…………………………………………………45
4.1. Introduction……………………………………………………………………45
4.2. Build Parameter Characterization……………………………………………46
4.3. Material Selection……………………………………………………………50
4.3.1. Nylon 11 & 12 Settings, Properties, Setup………………………………51
4.4. Experimental Setup & Methodology…………………………………………52
4.5. Pressurization Results for Test Specimens…………………………………54
4.5.1. Flat Deflection Test Piece…………………………………………………54

4.5.2. Curved Deflection Test Piece……………………………………..…..59
4.6. Pressure Deflection Discussion……………………………………………....65
4.7. Conclusion……………………………………………………………..…..66

CHAPTER 5: CONCLUSIONS & FUTURE
RECOMMENDATIONS…………………….………..…..…..…..…..………..67
5.1. Conclusions……………………………………………………………..…..67
5.2. Selective Laser Sintering Variance and Recommendations…………………..…68
5.3. Experimental Data Collection Error and Recommendations………………..…...70
5.4. Future Work…..….………………………………………………………..….71

Appendix A: Volume Actuation Concepts……………..…………………….……….…74
A.1. Inflation Concepts……………………………………………………………74
A.2. Non-Inflation Concepts…………………………………………………........84

Bibliography…………..…..…………..…..…..………………………………….....89

Vita……………………………………………………………………...……….93

List of Tables

Table 1: Mechanical Properties of Sintered Nylon Powders……………….….…….26
Table 2: Displacement Limits of Equation Accuracy……………………….……….32
Table 3: Pressure Limits of Equation Accuracy………………………………...33
Table 4: Inverse Stiffnesses of Nylon Powders…………………………….….…….34
Table 5: Nylon 12 Design of Experiments Build Parameters…………….…….…48

List of Figures

Figure 1.1 Below Knee Prosthetic Socket and Leg……….…………………………...….2
Figure 1.2 Trastibial Amputee Leg Anatomy…….……….…………………………...….2
Figure 1.3 Selective Laser Sintering Schematic……….………………..….….……..…...3
Figure 1.4 Actively Actuated SLS Prosthetic Research Procedure…………………..…...6
Figure 2.1 Measurement and Rectification Stages of Socket Manufacture…………..….13
Figure 2.2 Hexagonal Slotted Rosette……………………………………...…...…..17
Figure 2.3 An SLS Socket with Thin Wall Compliance…………………….…………...18
Figure 2.4 Non-Linear Compliant Feature Integrated Into a Full Socket……………….….19
Figure 3.1 Single Uniform Bladder Concept……………………………………….23
Figure 3.2 Multiple Linked Bladders Concept (a) & Inflating Plates Concept (b)….…...24
Figure 3.3 Multiple Independent Bladders……………………………………………24
Figure 3.4 Flat Pressure Test Specimen…………………….……………….…….….…..29
Figure 3.5 Flat Test Specimen (side view) with Three Membrane Thickness Options.…29
Figure 3.6 Wire Cleaning Tool Used to Scrape Part Cake from Inner Cavity………….…30
Figure 3.7 Linear Deflection Pressurization Results for Nylon 11 & Nylon 12….……...34
Figure 3.8 Linear Deflection Curve Requirement for Nylon 11 & Nylon 12…………....36
Figure 3.9 Typical FEA Deflection of Flat Plate Specimen……………………..…....37
Figure 3.10 FEA Deflection Pressurization Results for Nylon 11 & 12………………...38
Figure 3.11 Comparison of Nylon 11 Pressure Displacement Curves……..……..……..39
Figure 3.12 Comparison of FEA Results to the Required Deflection…………………...39
Figure 3.13 Redesigned Curved Specimen (side and top view)……………..…..….………41
Figure 3.14 Typical FEA Deflection of Curved Specimen……………………….……......42
Figure 3.15 FEA Deflection Pressurization Results for Nylon 11 t1.0 Curved Specimen……………………………..……………………….…………...43
Figure 4.1 Nylon 11 Design of Experiments Setup……………………...……..……...48
Figure 4.2 Sample Test Build for the DOE……………………….…………………...49
Figure 4.3 Nylon 12 Density vs. Andrew Number Results……………………………...51
Figure 4.4 Nylon 12 Modulus of Elasticity vs. Andrew Number Results…………….....51
Figure 4.5 Experimental Test Setup…………………………………………………..52
Figure 4.6 Flat Specimen Nylon 12 Inflation vs. Pressure Results……………………...54
Figure 4.7 Deflection Pressure Curves for Nylon 12…………………….……………56
Figure 4.8 Predicted vs. Actual Deflection Pressure Curves for Nylon 12 t1.3mm……..57
Figure 4.9 Flat Specimen Nylon 11 Inflation vs. Pressure Results……………………...58
Figure 4.10 Deflection Pressure Curves for Nylon 11…………………………………...59
Figure 4.11 Curved Specimen Inflation vs. Pressure Results…………………………....60
Figure 4.12 Comparison of Experimental Deflection of Curved Specimen to FEA….…61
Figure 4.13 Comparison of Experimental Data and FEA for Curved Specimen……..…..62
Figure 4.14 Repeated Inflation Cycling of Curved Specimen……………………….…..63
Figure 4.15 Repeated Inflation Cycling of Curved Specimen (Zoom)…………………..63

Figure 4.16 Representative Deflection Pressure Curves for Varying Thicknesses (Nylon 11)…………………………………………………………………………..64

Figure A.1 Inflating Plates Concept Views……………………………….……………..74
Figure A.2 Possible Movement of Limb within Socket…………………………………75
Figure A.3 Multiple Dependent Bladders Concept Views………………………………77
Figure A.4 Possible Pressure Hotspots on Residual Limb………………………………78
Figure A.5 Multiple Independent Bladders Concept Views…………………………….80
Figure A.6 Single Global Bladder…………………………..…..…………………….82
Figure A.7 Exploded View of Insertable Bladder Concept…………………………...85
Figure A.8 Rotary Spring Concept……………………………………………………86
Figure A.9 Collet Concept Isometric View (a) and Section View (b)…………… ……..87
Figure A.10 Pipe Clamp Concept Views……………………….……………………..88

Chapter 1

INTRODUCTION

1.1 Introduction to Area of Research

The prosthetic socket is the portion of the prosthetic leg that attaches to the residual limb. We have all experienced the phenomenon of feet swelling after standing and walking for long periods of time. Shoes are commonly made from flexible material like cloth or soft leather, so this swelling can be accommodated. The same phenomenon occurs for an amputee's residual limb. However, prosthetic sockets are generally stiff and have little to no compliance. Studies have shown residual limb volume can vary -11% to 7% in a single day due to changing activity level or weight. However, volume changes of only 3% to 5% can cause users to have difficulty putting on their prosthetic sockets (Greenwald, 2003). The improper fit that results can cause problems with gait and health issues. Many existing volume compensation methods are cumbersome, rely on the amputee to maintain the appropriate pressure level, or allow only for a decrease in limb volume. Automatic compensation for volume gain and loss is therefore needed; however, the complexity of designing such sockets renders traditional fabrication methods cost prohibitive or technically infeasible.

This research focuses on below-knee (BK) amputees, with an amputation occurring through the tibia (Figure 1.1).

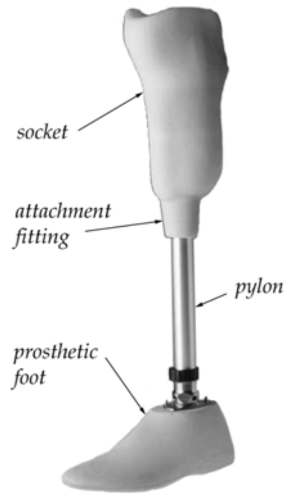


Figure 1.1: Below Knee Prosthetic Socket and Leg (Stevens, 1999)

As discussed above, the socket is designed to support and transmit the forces of movement from the residual limb (Figure 1.2). It is also designed to do this comfortably and there are usually two high pressure areas that must be accommodated: the distal tibia and the fibular head.

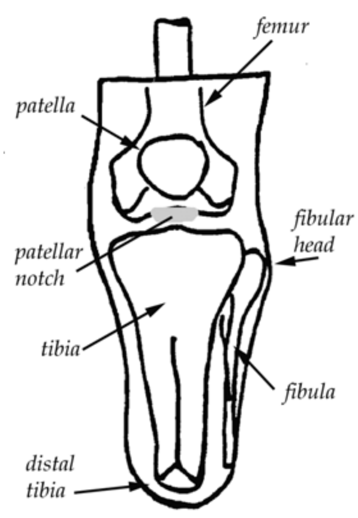


Figure 1.2: Transtibial Amputee Leg Anatomy

Selective Laser Sintering (SLS), an additive manufacturing (AM) technology, addresses both of these concerns. SLS is a layer-based AM technology that relies on a high power laser to fuse powder particles into a solid object. SLS fabricates parts directly from a 3D CAD model and provides virtually unlimited geometric freedom in the design of parts. Previous research has demonstrated the manufacture of prosthetic sockets with passive compliant regions using SLS (Rogers, 2007). Based on this SLS AM technique, steps toward developing a transtibial nylon prosthetic socket that automatically adapts to volumetric changes in a residual limb will be described.

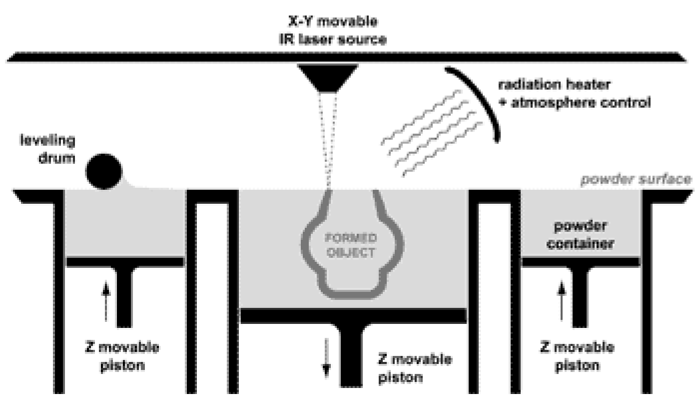


Figure 1.3: Selective Laser Sintering Schematic (Rapid Prototyping for Baghdad, 2009)

1.2 Focus of Research

Previous sockets developed at the University of Texas at Austin (UT) have had an adaptive capability, but have been passive and only accounted for positive volume changes. In the pursuit of an active actuation method, one of the strongest and most viable results was investigated inflation. Inflation based designs are attractive due to the potential they offer in design and implementation of all subsystems. The inflated membranes can be tailored in size, location and deflection characteristics. Additionally, inflation of such a bladder could be powered by energy harvested from the patient's gait.

1.3 Objective

The objective of this research is to design, develop, and manufacture a prosthetic socket that is actuated by inflation of an inner membrane. The target manufacturing technology is SLS. The socket must meet the following three performance criteria:

- The socket must allow a ± 10% volume change globally. This feature is the current focus of the project.
- The socket must have the capability for localized change.
- The socket must be capable of responding with a time constant of no more than 1 second.

1.4 Thesis Layout & Organization

This design will be completed in four broad stages. The first is to establish a patient need for this product, followed by investigation into possible solutions. Solutions include designs and manufacturing methods. Both of these areas need experimental investigation and validation. Finally, the future work beyond this research will need to be addressed. A more detailed overview is provided below:

Stage I, Literature Survey: In Chapter 2, the foundation of this research is established by laying out patient need. This need is established by reviewing medical and biomechanical research detailing current patient health and gait problems caused by inadequate sockets. Additionally, a survey of the market and current state of the art research has been completed to demonstrate a lack of solutions for this problem.

Stage II, Concept Generation & Initial Design: In Chapter 3, total socket concept generation is described. These concepts were evaluated and scaled down for testing. Selective laser sintering is presented as the most viable manufacturing method.

Stage III, Experimental Work: In Chapter 4, the parameters involved in an SLS build are presented in relation to their effects on flexibility and density for several standard powder types. Once a relationship between these variables was determined, an optimal build setup was selected. An initial design, completed in Stage II, was tested for deflection characteristics and the curved specimen also developed in Stage II was also tested and compared.

Stage IV, Future Work: In Chapter 5, conclusions are made regarding work completed thus far. Recommendations for future experimental work and the minimization of error sources are presented. The next steps for the work completed in this project as well as the long-term development of an actively actuated prosthetic socket are also discussed.

Figure 1.1 shows a flow chart of this research and its major focus areas.

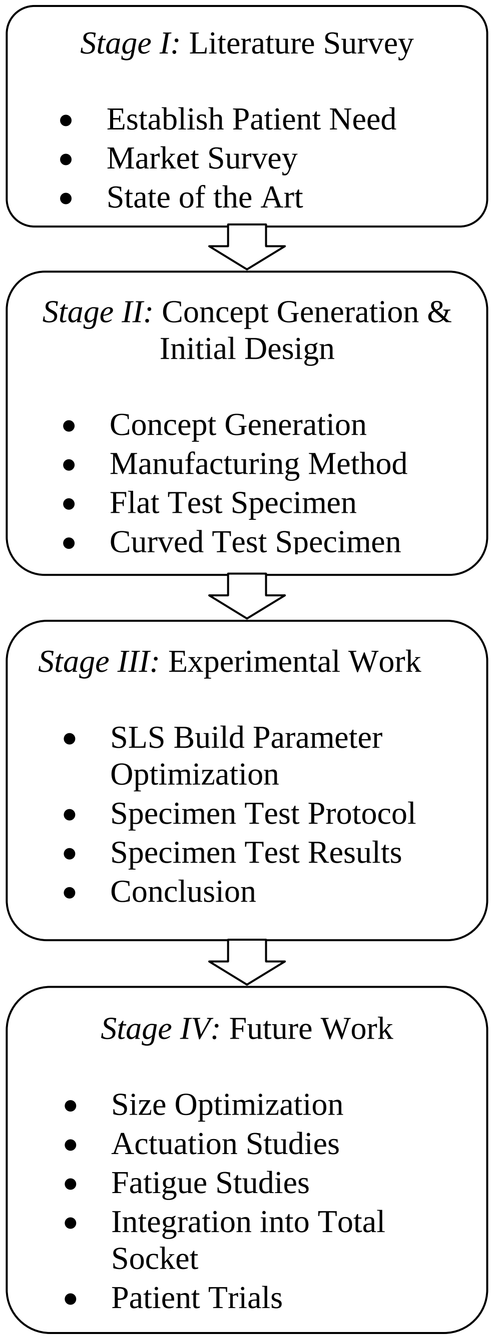


Figure 1.4: Actively Actuated SLS Prosthetic Research Procedure

The work presented in this thesis outlines the initial work done to complete a socket capable of being used by a trans-tibial amputee. It establishes the need for such a device and provides research and analysis into the feasibility of an inflation based concept using smaller deflection test pieces. Preliminary analysis of possible actuation methods is provided. Finally, recommendations for the continued development of an actively actuated prosthetic socket are provided.

Chapter 2

BACKGROUND

This chapter explores past work on socket manufacturing as well as the current state of the art in literature and industry. These areas are presented with a focus on establishing patient need. Finally, Selective Laser Sintering (SLS) is posed as a possible solution for the problem and an overview of past research into sockets produced by SLS is discussed.

2.1 Prosthetic Socket Overview

Amputation is, by its very nature, a traumatic event. The injuries leading to amputation can greatly vary—vascular disease, cancer, accidents, etc.—but every procedure results in a radical change in lifestyle for the patient. This research focuses on one particular group of amputees, specifically lower limb, below knee (BK) amputees, also referred to as transtibial amputees.

A socket is the primary interface between the patient and the prosthesis. It exists to attach the prosthesis to the patient and to transmit forces from the patient to the prosthesis for purposes such as walking. There are two primary types of BK prosthetic sockets (Tang, 2008). The standard socket is the patellar-tendon bearing (PTB) prosthesis. This socket concentrates much of the pressure—as much as 44 to 58 psi (300-400 kPa; Beil, 2004)—on the patellar tendon and medial tibial flair, which can result in health issues. An alternative to this is the total surface bearing (TSB) socket. Utilizing suction, it creates a seal around the limb and distributes the resulting pressure created by use evenly across the limb. TSB sockets are reported to have greater patient satisfaction, but are sensitive to changes in volume.

2.2 Customer Need

Without question, the number one issue for patients with their prosthetic sockets is comfort. This priority is clearly evident from the sheer number of papers that reference or directly address patient comfort. It is a difficult subject to approach because of its variety in both definition and possible sources. There have been numerous studies investigating these areas, which will be discussed below.

Fit of the socket to the residuum is critical to patient comfort, and is the most heavily addressed topic (Legro, 1999). Because most patients use their sockets frequently and for long periods of time, the comfort of such sockets is much more important than a device with occasional or light use. Unfortunately, fit and comfort are very difficult to define consistently. In fact, there are no universal measures or standards for socket comfort, so many studies resort to statements such as “Socket fit and alignment were verified by a certified prosthetist” (Smith, 2006). This variance in definition is to be expected, since residual limbs differ so much from patient to patient. Length of the prosthetic socket alone can vary from two inches below the knee to just above the ankle, with a preferred length of 6 in (Tang, 2008). Similarly, the remaining bone structure and limb circumference can vary significantly between patients.

This research project addresses one particular source of patient fit and comfort, volume changes. Immediately after amputation, most patients will experience muscle atrophy that significantly diminishes the volume of the residual limb (Fernie, 1982). This process is called “maturation” and is usually controlled through a compressive stump shrinker (Tang, 2008). After this process is completed, a subject is typically fitted with their first long-term socket.

BK amputees experience two types of volume change. The first is a long term result of muscle atrophy and weight gain. Muscle atrophy occurs mostly in the first year, but continues well afterward with degeneration averaging 12% within the first three years (Fernie, 1982). Weight gain is another issue that can cause volume change. In the same study, every patient gained weight within two years of amputation (Fernie, 1982). Noted weight changes ranged “from approximately 2% in 1 year to 30% in 2 years”. At present, no sockets encountered are designed to accommodate this type of volume change. Some patients also use additional socks as a temporary stop-gap until total socket replacement, can be arranged.

The second type of volume change is much more rapid change, occurring on a daily and even hourly scale. Simple use of the socket, such as standing or walking for a half hour, can result in dramatic volume changes (Zachariah, 2004). Zachariah, et al. report volume increases between 2.4% and 10.9% with a median of 6.0% (standard deviation of 3.6%). Other studies show volume changes between -11% to 7% in a single day due to changing activity levels or weight (Greenwald, 2003). That study notes that volume changes of only 3% to 5% creates problems for donning the socket.

Most sockets have very little capability to accommodate changes in volume; those that do are designed to only accept positive changes. As previously noted, many patients carry additional socks that they add throughout the day to accommodate volume loss (Biel, 2002). The same is true for long term volume loss: patients initially fitted with one sock may need to go up to two or three socks between fittings.

While fit and comfort are the most important issues for patients regarding sockets, it is should be clear at this point that these issues are consistently ranked very low in patient satisfaction (Dilligham, 2001; Pezzin, 2004).

2.3 State of the Art

Many PTB sockets are built in-house and are custom tailored to the patient. PTB sockets are well-established, therefore most current research focuses on TSB sockets.

The most advanced transtibial socket on the market is the Otto Bock Harmony, also called the Vacuum Assisted Suspension System (VASS). The Harmony uses an active pump to draw a vacuum on the thin gap between the liner and the outer shell. The residual limb maintains such a close interaction with the liner that it as though the vacuum were being drawn against the limb itself. That negative pressure serves the two functions of keeping the prosthesis attached to the limb and helping to maintain patient limb volume (Street, 2007). The vacuum drawn need not be large, only 3.6 psi to 8.7 psi (250 to 600 mbar) on the Harmony E-Pulse (Otto Bock). In other ways, the socket is a traditional total surface weight bearing socket. While the socket can help to prevent daily volume changes associated with varying short duration activities, it cannot accommodate large or lasting volume changes. Any volume change must be addressed by adding additional socks because the addition of any specific pressure regions will cause a loss of the total surface bearing nature of the socket (Street, 2007).

This field is quite active with new intellectual property as evidenced by the number and diversity of patents. One interesting example is the “Inflatable Limb Prosthesis With Preformed Inner Surface” (Gosthnian & Herr, 1990). The socket is designed to minimize applied pressure throughout the socket by using multiple independent bladders. The bladders can be inflated to alter the stiffness. The inventors suggest that the inflation could be controlled by the user, implying that the compliance is passive. This patent fails to acknowledge the grander purpose that can be accomplished with inflation, namely, controlling and accommodating changes in residual limb volume. Finally, the patent makes no suggestion as to how this socket will be built.

Additional research is focused on new and revolutionary ways of building the PTB and TSB sockets. Another advanced TSB socket is the Össur Icecast Anatomy (Össur, 2009). This socket is designed to be cast directly on the patient using a pressure bladder to conform to the patient’s leg. This removes many steps from a traditional Plaster of Paris casting method. The result is a total surface bearing socket that can accommodate different types of suspension (pin, lanyard and valve).

One of the most exciting methods to emerge is rapid prototyping (RP), which has generated new possibilities for patients, prosthetists and designers. For comparison, a traditional socket is made in three stages: measurement, rectification, and fabrication (Ng, 2002). The first two stages are shown in Figure 2.1 below. Measurements are taken of the limb by a prosthetist and then a plaster wrap cast is used to create a negative (Figure 2.1a). This mold is filled to become a positive (Figure 2.1b). Clear plastic is draped (Figure 2.1c) over the positive to create a check socket, which is tested on the patient (2.1d) to determine areas that need additional relief or support. The final socket can be made of a hard plastic or carbon fiber or a number of other materials. The process is unique to each patient and prosthetist and exact replication of a socket is difficult. The process is labor and time intensive with a high skill requirement.

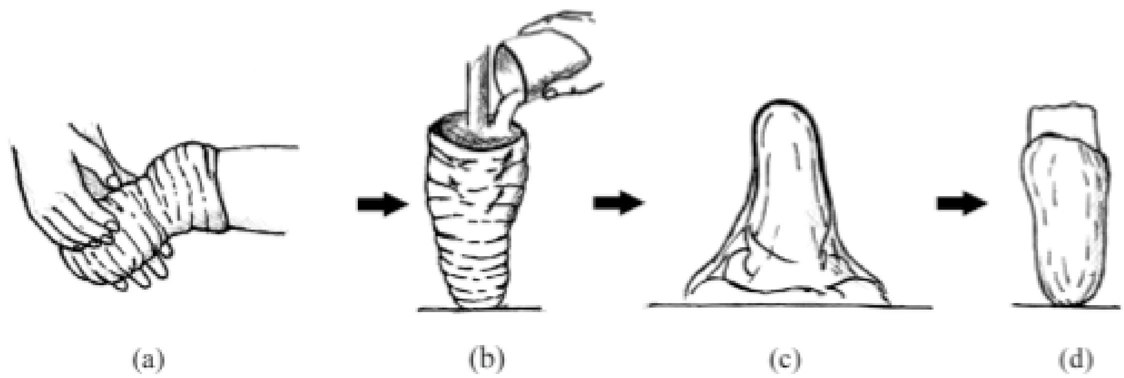


Figure 2.1: Measurement and Rectification Stages of Socket Manufacture (Ng, 2002)

Rapid prototyping can remove many of the steps involved with this process including the need to create any cast at all, while simultaneously giving the prosthetist more control. In place of casts, most RP socket manufacturing techniques utilize a 3D scan of either the patient's actual leg or the positive created for the check socket. Crucially, RP is significantly faster than traditional processes and is largely automated, which is a vital improvement (Ng, 2002).

There exist a number of rapid prototyping technologies, many of which have been used to build complete sockets. One such method is Fused Deposition Modeling (FDM) which extrudes molten plastic in thin streams to build a part through successive layers. It uses Polypropylene (PP) as a material. One study created a complete and functional PTB socket in under 4 hours using a custom designed FDM machine (Ng, 2002). It is currently being tested for bending and buckling.

Similar work was undertaken with a computer numerically controlled (CNC) extruder over a part bed (Rovick, 1994). The study resulted in a full-size 9 inch socket in 90 minutes. The socket was built with 300 layers, which was deemed enough to create a smooth finish. The study also included an initial estimation of fatigue life and found sockets should have a long life with typical use. Two sockets built with this method were given to subjects and have been successful for at least one month.

Another freeform fabrication method is Stereolithography (SLA) which is the most commonly used type of RP. SLA creates a part by firing a laser at a pool of ultraviolet sensitive resin to solidify a layer, which is then submerged to create a new layer. This process is repeated to create a total part. One study evaluated the manufacturing on the basis of cost and time (Freeman, 1998). The authors determined that it was possible to build functional BK sockets, but that the time it took (9 to 26 hours) and the capital cost ($145,000 to $490,000) did not justify use of the method at that time.

2.4 Selective Laser Sintering

Another RP technology has emerged that has potential for socket manufacturing. Selective Laser Sintering is an additive manufacturing (AM) process that builds a three-dimensional part by depositing successive layers of nylon powder and sintering them to lower layers. The process was first developed at The University of Texas (UT) at Austin (Deckard, 1986; Deckard, 1988).

The basic build process begins with mixing powder, either virgin or powder incorporated from previous builds. Powder is loaded into the machine and the settings are locked in using an attached computer. The actual build occurs in a nitrogen gas-rich environment as the laser sinters the parts. The powder is heated to just below its melt temperature and then the laser adds enough energy to cause the phase change to liquid, which subsequently cools to a solid. New powder is added in thin layers across the entire build surface, not just in the area where the part is being built. Because the same amount of powder is used if the build contains parts that are only one small area or covering the entire build area, builds are thus cost limited by total height of the parts in the build rather than volume as in most other manufacturing methods.

When the build is completed, after cool down, the powder from the part chamber is collected and moved to a break out area. The parts must then be removed from the non-sintered powder, which is called “part cake”. Part cake can vary between a fine talcum powder and dense, brittle cake which must be scraped and sand/bead blasted from the part. It is important to design any part with gaps or crevices such that the part cake can be easily removed.

SLS has many benefits for a prosthetic socket manufacturing scenario. One such benefit is near total freedom of geometry. Constraints are that the part must be within the size of the build chamber (a possible issue for building full sockets) and that fine detail is sometimes difficult. Additionally, the process is largely automated. This automation means that there is a low skill requirement in comparison to other manufacturing techniques. By way of example, to machine a varying radius on a part requires a significant amount of machinist skill. But such a radius in an SLS part would not require any changes to the build process. One other benefit of automation is that the process is significantly faster than most other manufacturing methods, and requires very little "active" time for the user. The machine, once started on a build, requires no user intervention until completion.

The process does have some drawbacks. The two most significant are high cost and the variability in the material properties (which will be discussed in the next chapter).

2.5 Previous SLS Work on Prosthetic Sockets

With the history of SLS at UT, it is not surprising that there has been much research completed in the past on SLS sockets. This research has focused almost entirely on localized pressure relief of two areas: the fibula head and the distal tibia region (Figure 1.2). The broad categorization of solutions developed for pressure relief is variability in stiffness. The change in stiffness and the method of achieving that stiffness were explored primarily with changes in geometry.

There are abundant methods to generate stiffness mechanically. There are the coil springs, but also cantilevers, domes, torsion elements and filaments, which have all been explored for incorporation into an SLS socket (Stevens, 1999). Stevens suggested a hexagonally-slotted rosette for the two pressure relief areas (Figure 2.2). The design is a double wall socket with the outer shell providing rigidity and the inner space for the compliant features. Double-walled sockets, while effective, can have excessive weight and bulk.

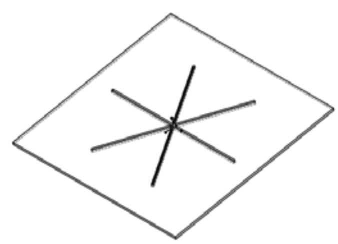


Figure 2.2: Hexagaonal Slotted Rosette (Stevens, 1999)

The simplest way of changing compliance for a Nylon material is a change in thickness (Lokhande, 2001). A socket was developed that had stiff thick sections to transmit load and support the patient, and thin sections in high pressure areas that allow pressure relief. The goal of this research was to develop a compliance model for designing the thin sections based solely on section thickness. The final solution (Figure 2.3) has the advantage of being single-walled and thus less bulky than other double-walled solutions.

Figure 2.3: An SLS Socket with Thin Wall Compliance (Faustini, 2004)

In order to gain more control over the stiffness and pressure relief, non-linear springs were researched (Faustini, 2004). This design (Figure 2.4) uses a soft rotary spring that provides initial pressure relief, but its travel is limited by the addition of a thin strip. This thin strip allows the introduction of a second stage of stiffness. The options and control of the compliance are promising and show the potential of SLS. The socket was tested in typical use scenario and reduced peak pressure 65.8% at the fibula head from 24.9 to 9.63 psi (172 to 66.4 kPa).

Figure 2.4: Non-Linear Compliant Feature Integrated into a full socket (Faustini, 2004)

Parallel to the research on adaptive volume change presented in this paper, other work on prosthetic sockets is being completed at UT for another user group, pediatric patients in developing countries (Vaughan, 2009). This research has identified a patient population with few resources and fewer solutions. The goal is to develop a socket that accommodates long term volume changes from year- to-year growth. Proposed solutions explored in this research include a ratchet mechanism to set a horizontal change, and a threaded screw pylon to allow for vertical growth of the residual limb.

2.6 Summary

As has been clearly demonstrated, there exists a need within the prosthetic patient community for a more comfortable socket that provides better fit. One source of the inadequate performance of current sockets is residual limb volume fluctuations, which is largely unaddressed by socket manufacturers. Selective laser sintering is an exciting new manufacturing method with great potential to impact the design and production of prosthetic sockets. It has significant advantages for the features of the socket (e.g. compliance, shape) that can be manufactured in no other way. Prior research into SLS sockets at UT has focused on local pressure relief. This research has focused solely on dissipating pressure by localized compliance, with stiffness set through geometry.

A survey of the literature indicates that global volume change can be a significant contributor to socket fit and comfort. This next chapter presents designs for a socket capable of global volume changes. It focuses on active compliance and studies the effects of material properties as well the geometry necessary to create a successful socket.

Chapter 3

DESIGN OF AN ACTIVELY ACTUATED PROSTHETIC SOCKET

Presented in this chapter are a number of possible total socket solutions designed to meet customer needs for an actively actuated prosthetic socket. The generated concepts are discussed and presented as excellent candidates for manufacture by Selective Laser Sintering (SLS). Two small test specimens were developed which will serve as proofs of concept as well as for verification of material properties and build parameters. Finally, possible actuation methods and schema are evaluated.

3.1 Introduction

After establishing patient need and a lack of existing solutions, the next step was development of possible solutions, particularly with respect to the design freedom that SLS provides. Concept generation focused on inflation techniques using the broadest techniques, as discussed below. However, methods of shape change beyond inflation were also created. Once concepts were narrowed down, it became important to re-examine SLS as the manufacturing technique. Does SLS still provide the best method? What challenges exist for the concepts because of the SLS manufacturing method? These questions will be addressed below.

Having elected to continue using SLS, the concepts discussed in the previous chapter were examined and two test specimens were created for initial evaluation. The specimens serve to verify material properties and thus machine parameters, as well as characterize the deflection-pressure relationship. Calculations and finite element analysis (FEA) are used to verify the designs before being built.

3.2 Concept Generation and Results

The first stage of the research involved concept development using various concept generation techniques, such as brainstorming and mindmaps (Otto, 2000). Since SLS is a freeform process, we are free to develop concepts that are not subject to the restrictions of traditional manufacturing techniques. The design space available is therefore much larger. However, designing with SLS also requires careful control of the material properties as well, since they are based on build parameters.

Concept generation was extremely broad with the one key function being “volume or shape change”. Categories of solutions included springs, clamps and inflation. The category with the most results was “inflation-based concepts” that featured local and global bladders. While there are many ways to accommodate shape changes, inflation is desirable for its combination of easy shape and stiffness control with controlled actuation. Inflation is by its nature active; other methods of compliance, such as springs, are passive and require a separate actuation method.

The inflation concepts can be grouped into “single bladder” and “multiple bladders” categories. All of the concepts use a flexible inner membrane surrounded by a stiff outer shell. The stiff outer shell is equivalent to the socket wall on more traditional sockets. The membrane therefore expands inward toward the limb in place of (or in addition to) a normal liner. Implementation of the inner membrane differentiates the concepts.

The first and most basic concept is the Single Uniform Bladder concept (Figure 3.1). This concept features a thin membrane that is a simple offset of the outer socket wall. The membrane inflates and deflates uniformly and globally. Volume changes in lower-limb patients, however, are rarely uniform, so the remaining concepts provide ways to focus the inflation.

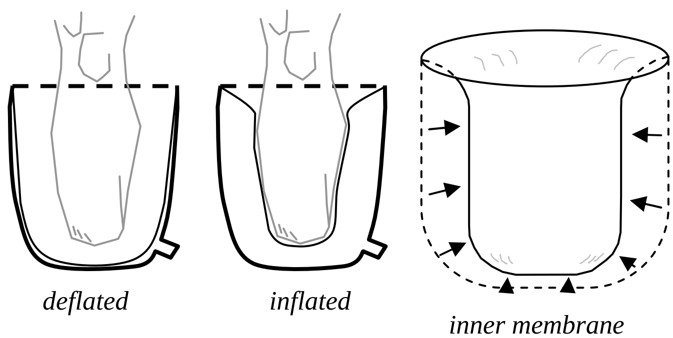
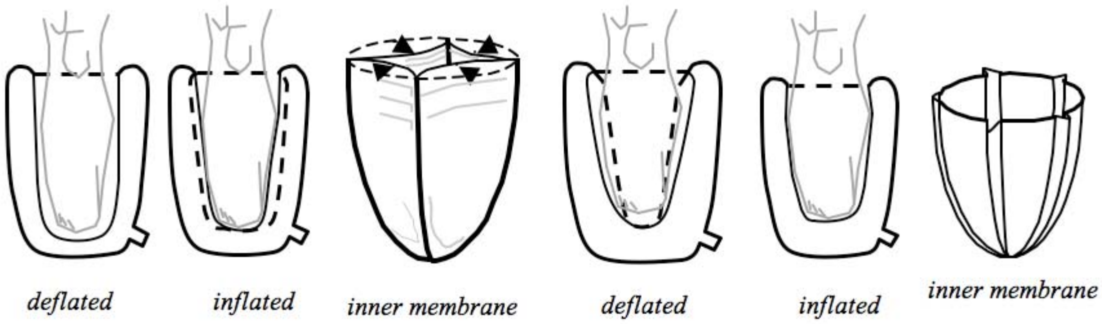


Figure 3.1: Single Uniform Bladder Concept

Still using a uniform global membrane, the Multiple Linked Bladders concept (Figure 3.2a) has fixed ribs that allow deflection only in areas that need it (as determined by the prosthetist). The inverse of this is the Inflating Plates concept (Figure 3.2b). This concept is made up of inflexible plates joined by flexible membranes. Inflating this concept moves the plates, theoretically providing better force transfer between the patient and the prosthesis. Additionally, since the plates are stiff, they are also capable of accommodating localized deflection mechanisms (such as those developed at The University of Texas at Austin (Stevens, 1999; Faustini, 2004).



(a) (b)

Figure 3.2: Multiple Linked Bladders Concept (a) and Inflating Plates Concept (b)

The final concept eschews global changes for a series of multiple independent bladders (Figure 3.3). Each bladder has a separate pressure source and control scheme. This design holds the most promise as it allows the prosthetist and the designer the most control over the socket's deflection characteristics.

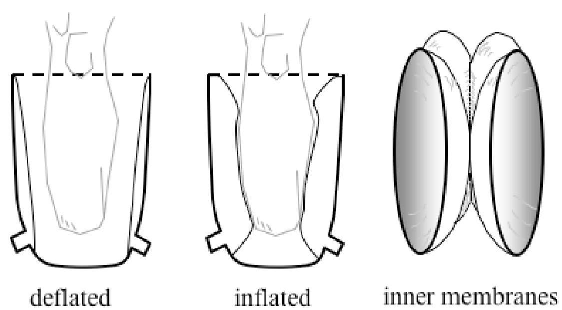


Figure 3.3: Multiple Independent Bladders Concept

These bladder based sockets are diverse in their solution to limb volume management, but also in their advantages and disadvantages. Developing them into fully functioning devices began in similar steps with inflation proof of concept models using simple shapes and then moving into developing more complex models and test specimens that more closely resemble the total socket concept.

As mentioned earlier, non-inflation based concepts such as threaded sockets, linear and torsional spring sockets and ones utilizing clamping analogies were also developed during concept generation. These are presented in Appendix A with brief descriptions and initial design impressions.

3.3 Designing Functional Mechanical Parts with SLS

The concepts discussed above could be built in a number of ways; however, it is only SLS that offers the ability to build one such socket as a single part. Other methods would require construction and assembly of several parts into a total socket. The process would likely require a number of different materials and manufacturing methods, significantly increasing overall complexity. SLS allows customization of each socket for each patient based on his or her needs as well as the advantages that result with a simpler design.

Previous work on prosthetic sockets at UT utilized nylon powders, as discussed briefly in the previous chapter. While the machine that UT has is capable of running any number of materials, the decision was made that previous research had provided sufficient evidence to continue along that design path. This section will discuss the mechanical properties of these nylon powders.

Nylon 11 and Nylon 12 are polyamide powders and belong to the same family of polymers as more common materials like polyethylene (PE), polyvinyl chloride (PVC) and polyester (Enderle, year). Typical mechanical properties relevant to inflation are shown below in Table 1.

Table 1: Mechanical Properties of Sintered Nylon Powders (CES Edupack, 2009)

Property	Nylon 11	Nylon 12
Density	0.0372 - 0.0379 lb/in^3	0.0365 - 0.0368 lb/in^3
Young's Modulus	180. – 190. ksi	174 – 203 ksi
Poisson's Ratio	0.406 - 0.423 (est.)	0.406 - 0.423 (est.)
Yield Strength	8.30 – 8.72 ksi	3.00 – 6.11 ksi
Tensile Strength	8.01 – 9.50 ksi	5.11 – 10.0 ksi

As can be seen, every material property has a variance, which is sometimes dramatic (e.g. Nylon 12 Tensile Strength). Most use of Rapid Prototyping (RP) or Additive Manufacturing (AM) is for prototyping parts that will eventually be built out of another material or with a different process, so the parts are used to model form only. In this research, however, the parts created will need to be accurate in both form and function. The function of inflation is highly related to density and Young's Modulus. So before any parts can be built, it is necessary to determine the optimal build parameters to create the desired mechanical properties.

3.4 Design of Deflection Test Specimens

Building total sockets is impractical for a number of reasons. They are not space efficient, either in relative density of "built" / "not built" area in the part chamber and they are exceedingly tall (nearly as tall as the entire build chamber itself). In the same space as a whole socket a large number of smaller test pieces can be built. It is possible in one build to fabricate dozens of small test pieces as opposed to a single total socket. Additionally, a whole socket is more difficult to test, since it is larger and is not necessarily easily connected to measuring devices or inflation sources.

The most promising designs are those that use a thin flexible membrane to achieve a shape change. The shapes that will be used in the final design will be irregular in overall shape. Designing and modeling a large organic shape is impractical and overly reliant on experimentation to quantify the relationships of deflection and pressure. A smaller, regular shape is much easier to model and requires less extrapolation to produce the various irregular shapes required in the final total socket design.

The choice was made to build a small test specimen that could be used to evaluate both material properties and deflection characteristics. The design was tailored to the selected test method of pneumatic inflation, to facilitate experimentation. These test specimens also serve as preliminary proofs of concept. If inflation is not possible or does not meet the performance criteria, then it can be eliminated without excessive time or energy investment.

3.4.1 Design of Flat Deflection Test Piece

Previous work at The University of Texas attempted to quantify deflection as a function of pressure (Lockhande, 2001). However, the experiments in this research could not achieve a seal on the test specimen, so a rubber gasket was used, which biased the results. Regardless, the design and setup used in that work are solid. The design used a thin circular membrane attached to a pressure source. A thin circular membrane is ideal in that it has a simple structure that is easy to build, has a known solution for deflection based on pressure, and it is easily verified using FEA.

The objective of the flat test piece is to build on that research. The design process was composed of three stages. The first step was to determine a general design. The second was to determine parameters for study and finally evaluate potential performance using hand calculations and FEA.

The first and most obvious design parameter was the membrane's size. Previous research discussed above (Lockhande, 2001) used a 2.0 in. diameter membrane. Prior designs completed at The University of Texas in passive localized compliance used an equivalent diameter of 3.94 in. (Faustini, 2004) and 1.5 in. (Stevens, 1999). Based on these sources, the choice was made to use a diameter of 2.0 inches. Lockhande's research concluded that a thickness of between 0.045 and 0.055 in. would provide the maximum flexibility for Nylon 12 without exhibiting any permanent deflection. Since Nylon 11 was investigated as well, and since there is no previous compliance testing history for Nylon 11, the first selected thicknesses were slightly outside that range, 0.0397 in, 0.0512 in. and 0.0709 in. (1.0 mm, 1.3 mm, 1.8 mm). These thicknesses were selected because they provide a range of possibilities from the thinnest that the machine can reliably build to a larger and hopefully impermeable thickness.

Instead of developing a separate test mechanism upon which a thin membrane would be placed, a design was completed that incorporates the membrane and an enclosure into a single unit that can be attached to the test rig (Figures 3.4 and 3.5). Integrating the membrane and enclosure reduces the number and complexity of attachments and, consequently, the possibility of leaks. It does, however, increase the size of the test specimen, which decreases the number that can be included in a single build. The static portion of the enclosure is designed to have a minimum thickness of 0.2 inches. This thickness is significantly oversized—between three to seven times the thickness of the membrane—to prevent any deflection or possible leaks due to low porosity.

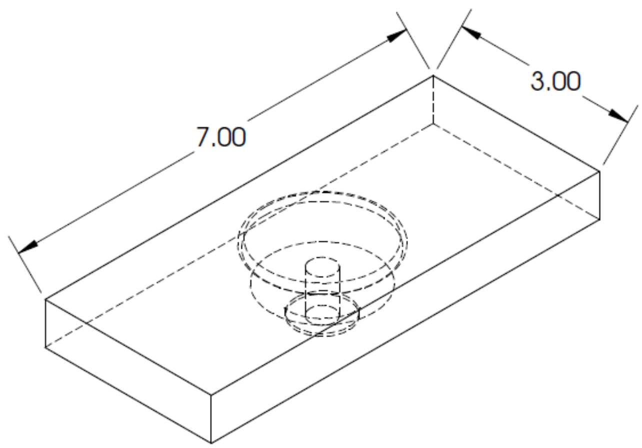


Figure 3.4: Flat Pressure Test Specimen (3/4 view)

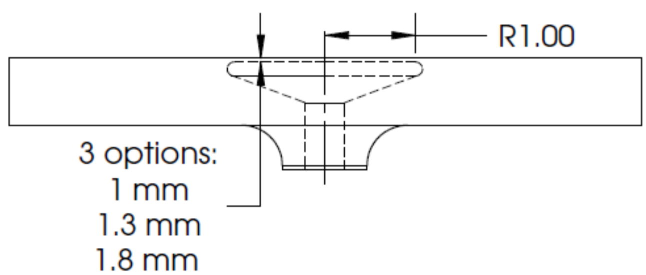


Figure 3.5: Flat Test Specimen (side view) with Three Membrane Thickness Options

The test piece is designed to accommodate a Quick Connect plug-type connector. This connector allows easy connection/disconnection to the pressurized air lines of the test apparatus. To facilitate the test protocol, thick flanges extending from the central membrane enclosure allow the specimen to be clamped down during the tests, preventing any movement which could create an error in the membrane's measured displacement. The first test piece built did not include any room to easily clean the remaining part cake from the build. A revision was quickly completed that added a bevel to ease cleaning. A wire-based tool was also created to give easy access to the more difficult to reach sections of the part, to further improve the cleaning process (Figure 3.6).

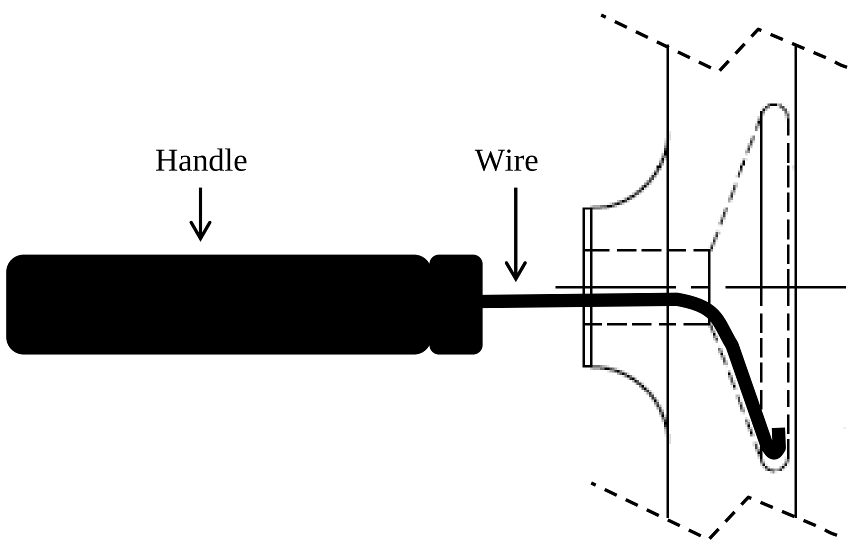


Figure 3.6: Wire Cleaning Tool Used to Scrape Part Cake from Inner Cavity

The design was modeled in Dassault Systèmes SolidWorks. The part was exported to the SLS machine in a .STL file format, the standard for RP machines.

3.4.1.1 Theoretical Evaluation

Before building any of these test pieces, it was important to determine if this design was likely to satisfy the design constraints. It was crucial to recognize whether reasonable deflection can be achieved with an acceptable pressure.

To answer this question, two methods can be employed: closed-form equations derived from experimental studies and published in handbooks and scholarly journals, or Finite Element Analysis. Both techniques can be applied for this simple design, but this will not be the case for the second test piece, as described later in this chapter.

3.4.1.2 Closed Form Equation for Plate Deflection

A closed form solution exists for a thin circular membrane undergoing deflection from uniform pressure (Machinery's Handbook 27th Edition, 2004) and fixed along the entire circumference:

$$d = \frac{0.0543WR^2}{Et^3}$$

where W is total load in pounds (or pressure times affected area) and d is displacement of the center. The only material property required is Young's Modulus of Elasticity (E). Geometric quantities include the radius of the membrane (R) and its thickness (t).

This equation asserts a linear relationship between applied pressure and deflection, and therefore is only valid at very small displacements. This equation requires four conditions for accuracy:

1) the thickness of the plate is not greater than one-quarter the least width of the plate;
2) the greatest deflection when the plate is loaded is less than one-half the plate thickness;
3) the maximum tensile stress resulting from the load does not exceed the

elastic limit of the material; and
4) all loads are perpendicular to the plane of the plate.

The validity of these assumptions for are addressed as follows:

1. Thicknesses of the plate are 0.0397 in, 0.0512 in. and 0.0709 in. and a radius of 1 in. generates ratios of thickness/diameter of 0.0397, 0.0512 and 0.0709, all below ¼ .
2. The largest deflection must be significantly larger than the thickness if the device is at all going to be successful in this application. The range of validity is summarized in Table 2 below.

Table 2: Displacement Limits of Equation Accuracy

Material	t = 1.0 mm	t = 1.3 mm	t = 1.8 mm
Nylon 11	0.0198 in.	0.0256 in.	
Nylon 12	0.0198 in.	0.0256 in.	0.0345 in.

3. Using the corresponding maximum tensile stress equation (Mach. 27th Ed, 2004),

$$S = \frac{0.24W}{t^2} = \frac{0.24(\pi R^2)}{t^2}q$$

and solving for W with S (elastic strength) set to the minimum ideal tensile strength (Table 3) of the materials allows determination of the maximum pressure (q) that can be applied while maintaining accurate results (Table 3).

Table 3: Pressure Limits of Equation Accuracy

Material	t = 1.0 mm	t = 1.3 mm	t = 1.8 mm
Nylon 11	16.74 psi	27.84 psi	
Nylon 12	10.67 psi	17.75 psi	34.04 psi

4. The test apparatus used was a pressurized air source and displacement was measured only after the pressure stabilized. Therefore, the assumption of perpendicularly applied loading holds true.

The equation is valid up to the point of pressure or displacement in the above two tables, whichever is lower. Even, with the presented limitations, the equation is still valid. It shows the initial displacement, and is also useful post-experimentation as a means of verifying that the assumed modulus agrees with experimental values. Combined with a understanding of the limits of the equation's application range described above, it is possible to experimentally verify Young's modulus, since that is the only material property in the equation.

Taking the original equation and solving for pressure (q) yields the following equation:

$$d = \frac{0.0543\pi R^4}{Et^3} q$$

The pressure-displacement curves for varying thicknesses and materials can now be plotted. The modulus of elasticity used was the midpoint of published ideal values

(188.5ksi for Nylon 12 and 184.2ksi for Nylon 11, as shown above in Table 1. These values were reevaluated after experimental analysis has been completed.)

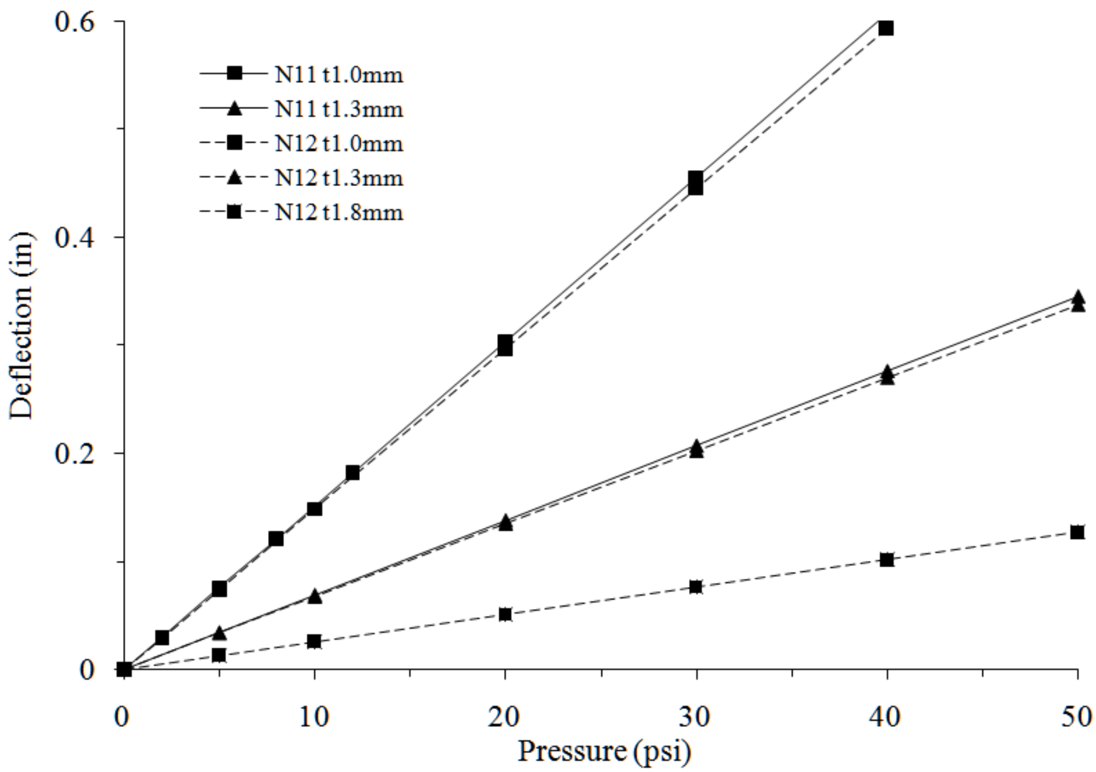


Figure 3.7: Linear Deflection Pressurization Results for Nylon 11 & Nylon 12

Table 4: Inverse Stiffnesses of Nylon Powders

Material	t = 1.0 mm	t = 1.3 mm	t = 1.8 mm
Nylon 11	0.015176 in/psi	0.0069077 in/psi	
Nylon 12	0.01483 in/psi	0.006748 in/psi	0.002542 in/psi

These theoretical curves are all linear and the slope is analogous to the inverse of stiffness. As expected, increasing the thickness of the membrane does produce an increase in stiffness. Additionally, the Nylon 11 and Nylon 12 stiffnesses are very similar, which is expected due to the similar nominal Young's moduli. Based on this result, Nylon 11 is a more promising material for the final design. However, since sintered parts can have such a wide range of possible mechanical properties, it is important to keep Nylon 12 as a candidate until parts are built. Parts were built out of Nylon 12 first. Based on the inadequate performance (discussed in the following chapter), the thickness of 1.8mm was ruled out for future builds of Nylon 11.

Now that a preliminary deflection pressure curve has been created, we can determine the deflection range that will actually be required for the socket to be successful. The posterior distal tibia socket end of the residual limb needs the largest deflection. A 6% volume change over a 2.45 in. radius region (as recommended by a prosthetist) requires 0.240 in. of deflection. Using a simple ratio based on diameter, the required deflection for a 1 in. radius membrane corresponds to a displacement of 0.112 in. Examining the linear pressure-deflection curves above, all of the thicknesses for both materials can achieve the required deflection.

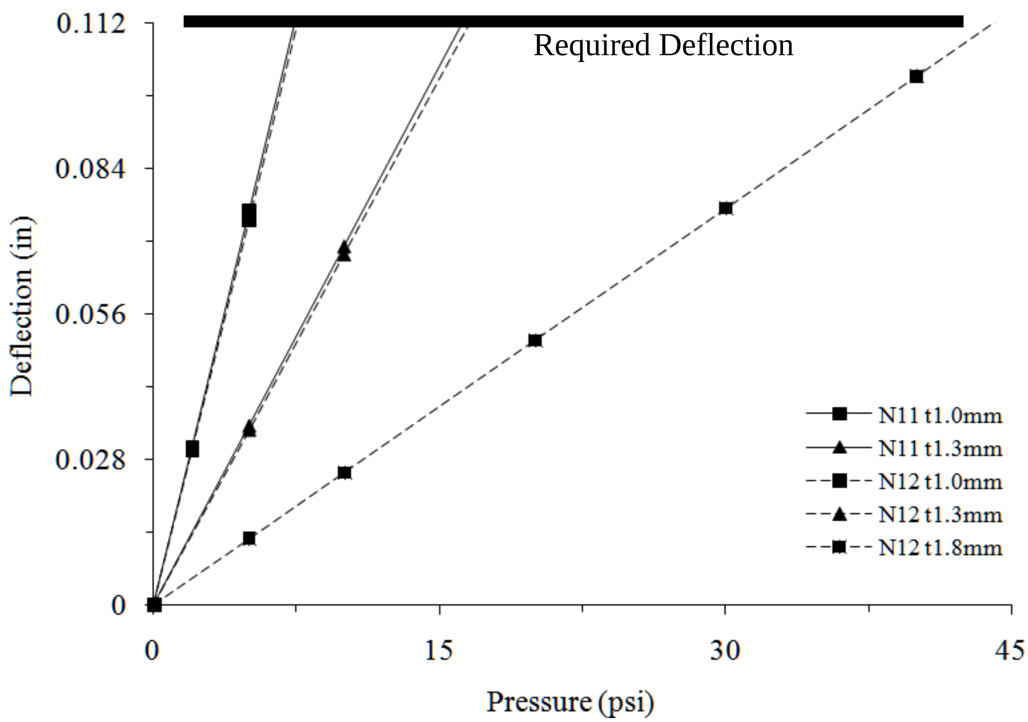


Figure 3.8: Linear Deflection Curve Requirement for Nylon 11 & Nylon 12

This deflection range does violate the flat plate assumptions, so a finite element analysis was conducted to better judge if the test pieces can meet the specifications. The actual performance of the test pieces is discussed in the following chapter.

3.4.1.3 Finite Element Analysis of Flat Plate Deflection

The closed-form solution is only useful at low pressures and small deflections, far lower than the actual operational pressure range. FEA allows a more accurate deflection calculation over a wide range of applied pressures, rather than just the initial pressures. Dassault Systèmes COSMOSWorks was selected as the finite element software package for its ease of use and integration with the selected modeling software, SolidWorks.

Additionally, it has large displacement calculation features, which will be necessary to model the membrane's deflection (Figure 3.8).

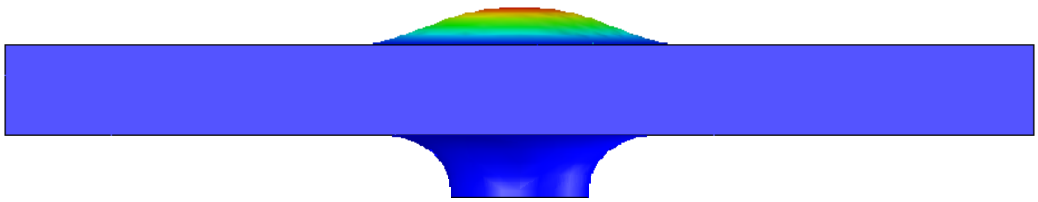


Figure 3.9: Typical FEA Deflection of Flat Test Specimen

The Computer Aided Design (CAD) solid models of the test pieces were meshed with between 38,000 and 44,000 degrees of freedom (13,000 to 15,000 nodes and 7,000 to 8,600 elements). The large displacement flag was checked for all simulations. COSMOSWorks solves large displacement simulations by applying the load gradually in a finite number of steps and using Preconditioned Conjugate Gradient (PCG) method with five variables of energy and residual norms to track convergence. The large displacement flag must be enabled because the expected deflection at maximum pressure can be over three times the nominal thickness of the membrane, which violates the small deflection assumptions most FEA programs are built upon. The convergence method applies the set load incrementally, rather than all at once. This increment approach increases the confidence in the result.

The FEA results (Figure 3.9) are promising and show a more reasonable curve shape, one similar to traditional stress-strain curves of ductile materials. Again, the trends of increasing thickness resulting in increasing stiffness, as well as Nylon 12 being stiffer than Nylon 11, are present. The accuracy of these models are revisited in a comparison of experimental data in the next chapter. The deflection of the Nylon 11 and

Nylon 12 test specimens are grouped similarly by thickness with material properties having only the slight effect of Nylon 11 being marginally softer. These trends mirror those from the linear deflection curves shown above.

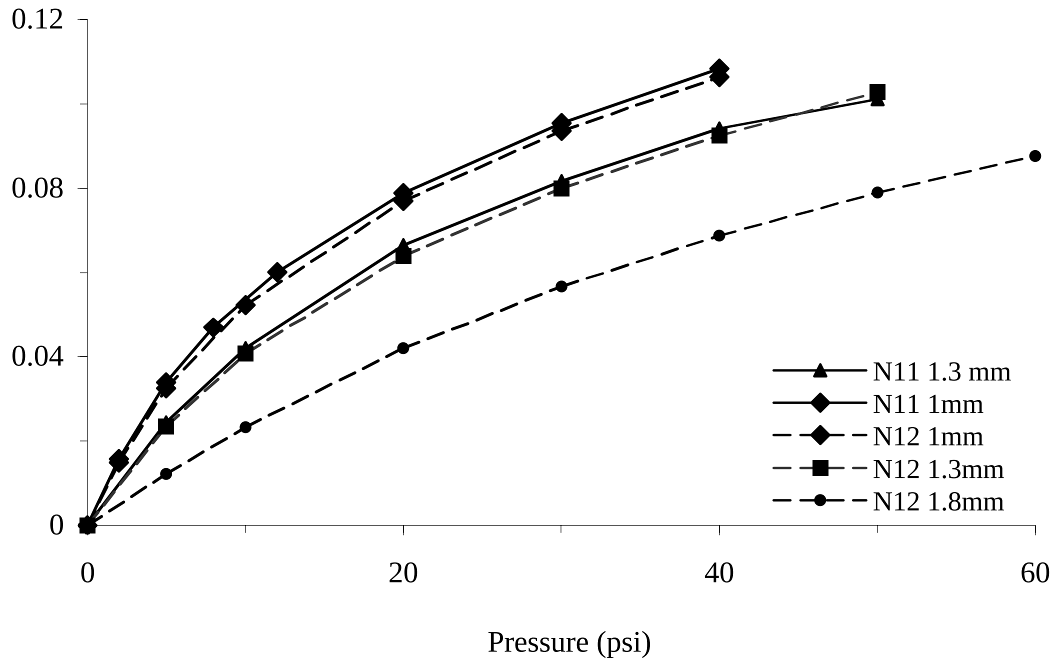


Figure 3.10: FEA Deflection Pressurization Results for Nylon 11 & 12

It is important to note that the FEA and the equation-generated curves are dramatically different (Figure 3.10 for Nylon 11. Nylon 12 has similar trends). This result is expected because of the limited range of accuracy from the closed-form equation.

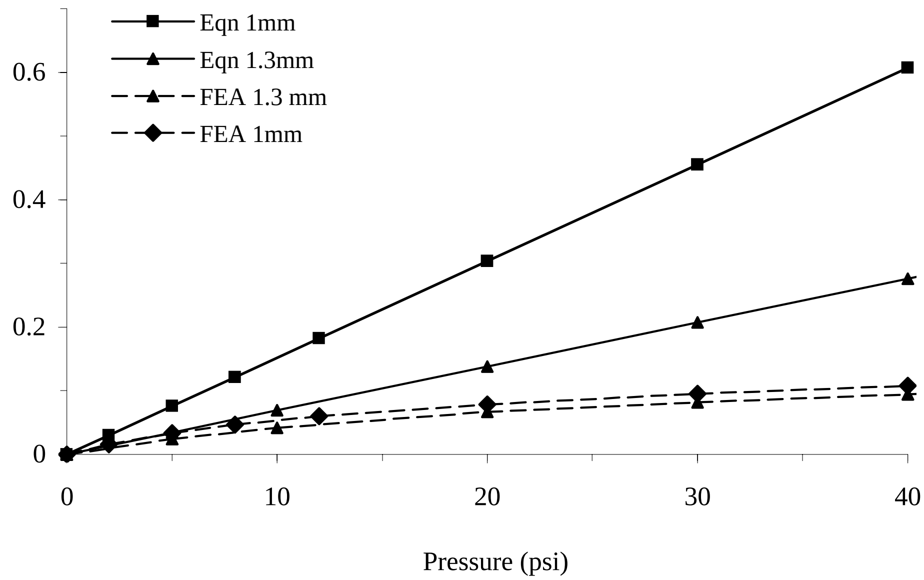


Figure 3.11: Comparison of Nylon 11 Pressure Displacement Curves

Comparing the results of the FEA to the required deflection of 0.112 discussed above shows that only the two smaller thicknesses of either material are likely to achieve that goal (Figure 3.11). The 1.8mm test specimen built in Nylon 12 could possibly achieve the 0.112 in displacement, but it would require a pressure range well beyond what is feasible with the intended pressure sources.

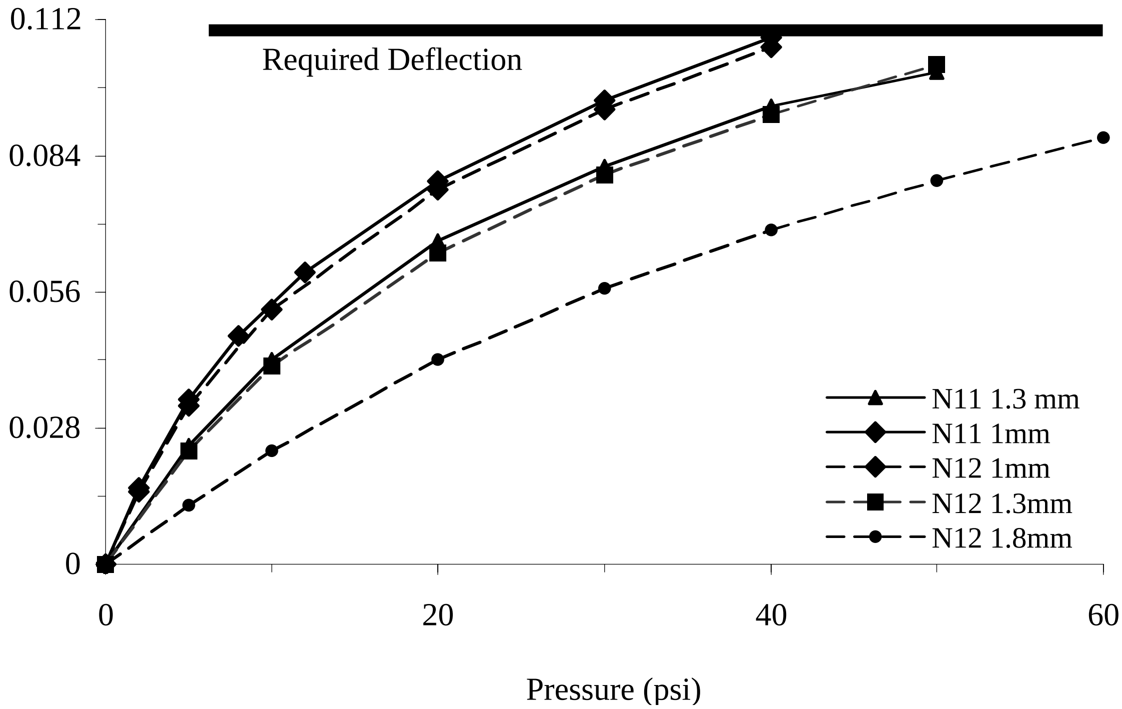


Figure 3.12: Comparison of FEA Results to the Required Deflection

The FEA was rerun after experimentation to ensure that the material properties used matched the actual parts built and is discussed in Chapter 4.

3.4.2 Design of Curved Deflection Test Piece

A second design was created from a hybrid of the earlier thin circular membranes and a membrane that could be implemented into the final design. The flat test specimen was used to determine material properties as well as function as an early proof of concept. However, after experimentation, it was concluded that the flat membrane was unable to achieve the displacement needed.

A curved design, one that more closely resembles an actual socket wall, has much different response characteristics that the flat design. Using a prosthetist's example of a

4.29 in. diameter area and a required 6% volume change (0.2401 in. deflection) as a starting point (Bosker, 2008), the flat test specimen was refined in size and layout. A half-scale model was constructed (Figure 3.12). The deflection necessary was 0.240 in, or at half-scale, 0.120 in. The 0.120 in deflection was split between the two sides of the neutral plane. The specimen therefore was built with a concave shape similar to the organic shape of the socket wall. The thickness was kept at 1mm, which was shown to be the thinnest that can be built with SLS. Additionally, the large stiff flanges were removed since they were no longer needed for clamping the specimen to the test rig.

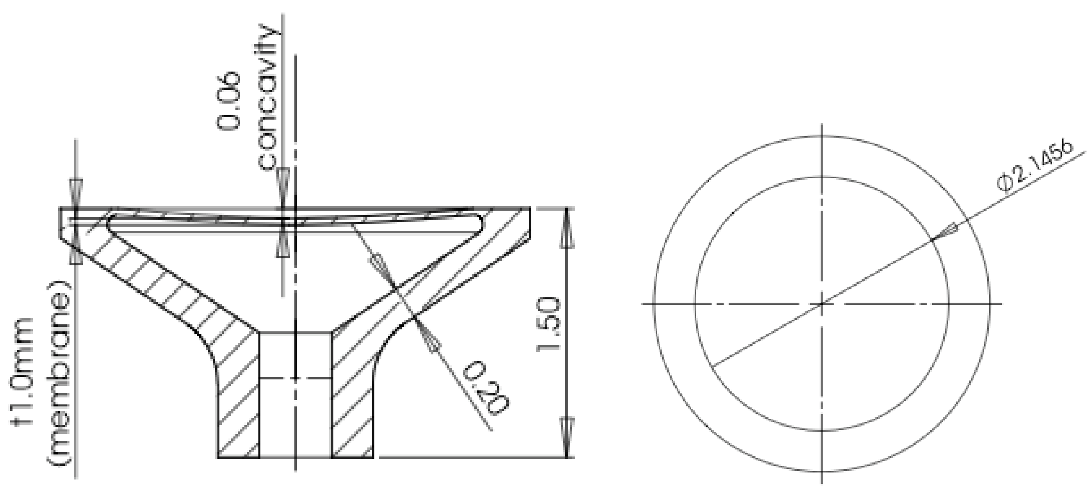


Figure 3.13: Redesigned Curved Specimen (side and top view)

Based on the experimental results of the flat test piece, it was determined that only Nylon 11, due to its lower stiffness, has the possibility of reaching the desired deflection. Therefore no Nylon 12 curved deflection pieces were built.

3.4.2.1 Finite Element Analysis of Curved Test Specimen

Finite element analysis, similar to that used on the flat test specimens, was conducted on the curved test specimens. A sample deflection profile is shown below (Figure 3.13). The results were generated using the large displacements option within COSMOSWorks and using a mesh with 44,000 total degrees of freedom (15,000 nodes and 8,600 elements).

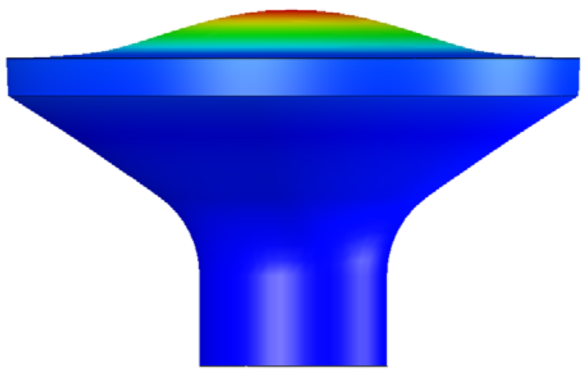


Figure 3.14: Typical FEA Deflection of Curved Specimen

The resulting graph for the curved specimen shows a different deflection pressure trend than the flat pieces (Figure 3.14). The curve has two stages: an initial stage of low stiffness for low pressures that then transitions into a higher stiffness at high pressures. The transition point is at approximately 2 - 4 psi. It should be noted that the curved specimen FEA for deflection is an order of magnitude lower than the flat specimen FEA results. No explanation can be given other than this being an artifact of the FEA process since both simulations used the same material data. This FEA implies that the curved test specimen will be unable to achieve the required 0.120 in. deflection. However, since these results are so dramatically out of sync with the prior FEA results, experimentation was used to actually characterize this part.

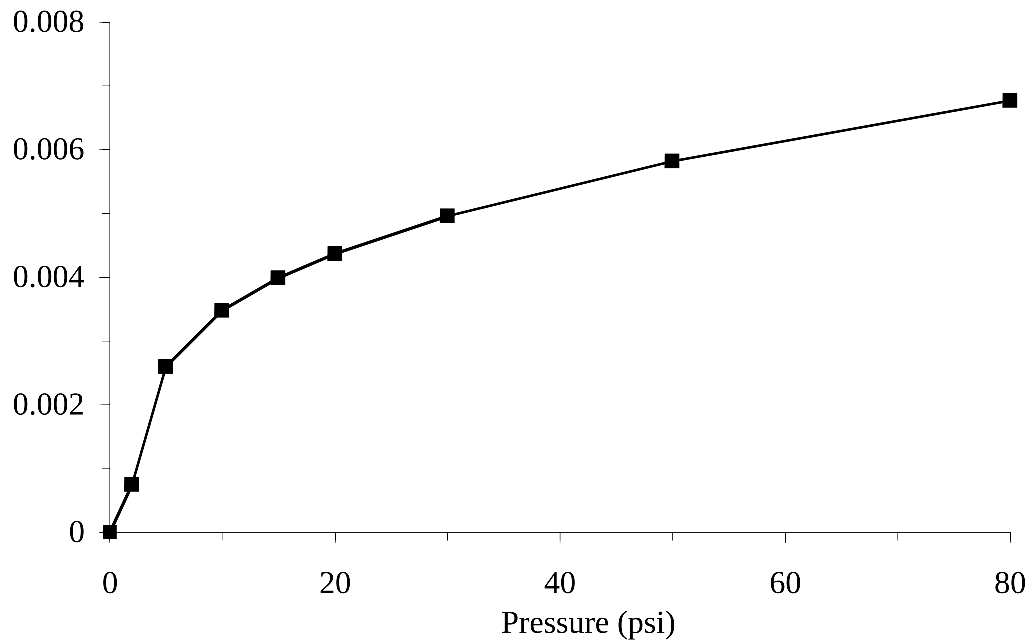


Figure 3.15: FEA Deflection Pressurization Results for Nylon 11 t1.0 mm Curved Specimen

3.6 Chapter Summary

In this chapter, possible solutions are presented to the previously described design problem. Concept generation led to numerous high level designs that could provide the necessary volume change. The first step in creating such sockets was to judge the deflection characteristics and material properties through use of a simple flat thin membrane. Both Nylon 11 and Nylon 12 were selected for investigation. The design uses several thicknesses and the flat membrane FEA shows that the thinnest two can satisfy the design constraint for deflection. This proof of concept led to development of a second test specimen, one that uses a curved, thin membrane. This thin membrane better approximates the actual shape of the socket wall and has much more promising deflection characteristics, being more flexible and requiring less applied pressure. The next chapter on experimentation evaluates these designs to determine whether they meet the design criteria.

Chapter 4

EXPERIMENTAL VERIFICATION OF AN ACTIVELY ACTUATED PROSTHETIC SOCKET

A systematic study of SLS build parameters is presented, using density and modulus of elasticity as driving variables. The Andrew Number is presented as a compact and repeatable measure for determining machine parameters based on desired part mechanical properties. Two inflation test pieces are developed and tested using a protocol which is described below. The test pieces are used to quantify the inflation-deflection characteristics of both Nylon 11 and Nylon 12. Experimental results are also compared to the predicted results developed in the previous chapter.

4.1 Introduction

Once the design phase was completed, an initial build was created with the flat test specimen at the machine's default build parameters. The Nylon 12 test pieces were unable to hold pressure straight from the build. The material was so porous that the high pressure shop air would simply blow straight through the deformable membrane. Several attempts were made at sealing the membrane, but were unsuccessful. It was determined that the parts needed greater density without sacrificing flexibility.

A Design of Experiments was undertaken to evaluate and select the best settings with which to build the parts. The study employed check parts and focused on the density and flexibility that can be achieved by changing the build settings that affect energy density. These parameters and the material properties achieved are presented below.

After the machine settings were selected, flat test specimens were built. Specimens were built first from Nylon 12, then from Nylon 11. The results from these early test specimens showed promise; however, they did not have the deflection necessary at a reasonable pressure. The curved redesign was then built using the more flexible powder, Nylon 11. The flat and curved test pieces are compared against the predicted results based on a closed-form equation and Finite Element Analysis. This validation will be important for future iterations of the test specimen.

4.2 Build Parameter Characterization

A vital task for this research project was determining the appropriate SLS process parameters for this application. For a concept to be successfully inflated, the membranes need to meet several material-based performance criteria. The first is extremely low porosity (high density). Whether using air, water or another inflation medium, the membrane needs to be impermeable to the fluid while under pressure. Secondly, the flexible membrane portions need to be highly flexible (low modulus of elasticity), while the outer shell needs to be rigid with little to no deflection under pressure. Both parameters (density and modulus of elasticity) are highly affected by energy input into the part during the sintering process. The Andrew Number (AN), shown below, is a quantification of energy concentration (Williams & Deckard, 1998).

$$AN = \frac{LP}{SS \cdot SSP}$$

The Andrew Number is a function of laser power (LP), scanning speed (SSP) and scan spacing (SS), typically measured in J/cm^2. All three parameters are functions of the laser used to sinter the part. Laser power is measured in Watts and can be set to any point between 'OFF' and the machine's maximum (for the machine used in this research, 100W). Scanning speed is the rate at which the laser moves across the part bed, measured in inches per second. Scan spacing is the distance between adjacent laser scan lines, measured in inches.

The University of Texas at Austin Mechanical Engineering Department operates a 3D Systems Vanguard HiQ Sinterstation (3D Systems, Rock Hill, SC), which was selected for use on this project. This Vanguard is used primarily with Nylon powders. The operating software for the Vanguard allows a large variety of parameters to be modified.

The Design of Experiments (DOE) method was used to find the optimal Andrew Number. The control parameters selected were laser power, scan spacing and part bed temperature (PBT). Laser power and scan spacing are two parameters in the Andrew Number. Scan speed, however, is a fixed parameter in the software (400 in/s) and cannot be manipulated. Part bed temperature was varied because, while it does not figure into AN, it affects both the energy flux into the part and the overall build quality. Issues such as curl, yellowing, and orange peel are all affected by PBT. A sealable, flexible part without geometric quality is unacceptable. PBT is a build parameter, meaning that it is set at a single value for the entire build. LP and SS can be set on a part-by-part basis.

With these three variables, the DOE was constructed for two builds for each powder. Each build was performed at a separate PBT with combinations of the LP and SS selected. Shown below in Figure 4.1 are the Nylon 11 DOE build parameters. Table 10 shows the Nylon 12 DOE setup. The parts selected for the DOE builds were a combination of tensile dog bones, flexure check pieces and density check pieces.

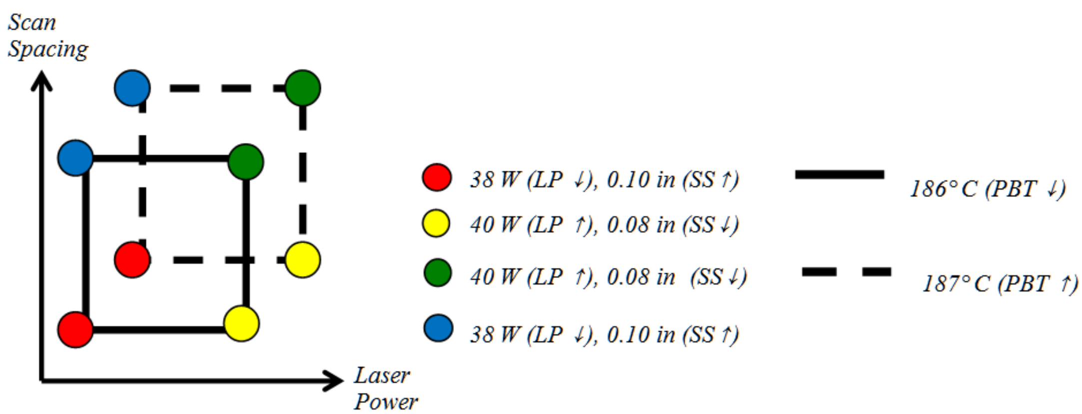


Figure 4.1: Nylon 11 Design of Experiments Setup

Table 10: Nylon 12 Build Parameters:

DOE Variable	Min	Max
Laser Power (LP)	43 W	45 W
Scan Spacing (SS)	0.008 in	0.01 in
Part Bed Temperature (PBT)	176° F	178° F

While Andrew number can be very helpful in providing a measure for evaluating material properties, it does not capture all of the information needed for a successful build. An Andrew Number of 1.5 J/cm^2 can be achieved in numerous ways, such as with a high laser power or a low scanning speed. While the Andrew Number for either would be identical, parts built at each setting could be very different. For example, a high laser power can produce "burn through" where part detail is lost.

Additional parts were included in the build to evaluate general part quality and eliminate problems such as curl and loss of part detail. These parts included thin-wall cubes for curl, and detail check pieces with fine writing and orientation markers for checking level of detail achieved. Figure 4.2 shows a sample build.

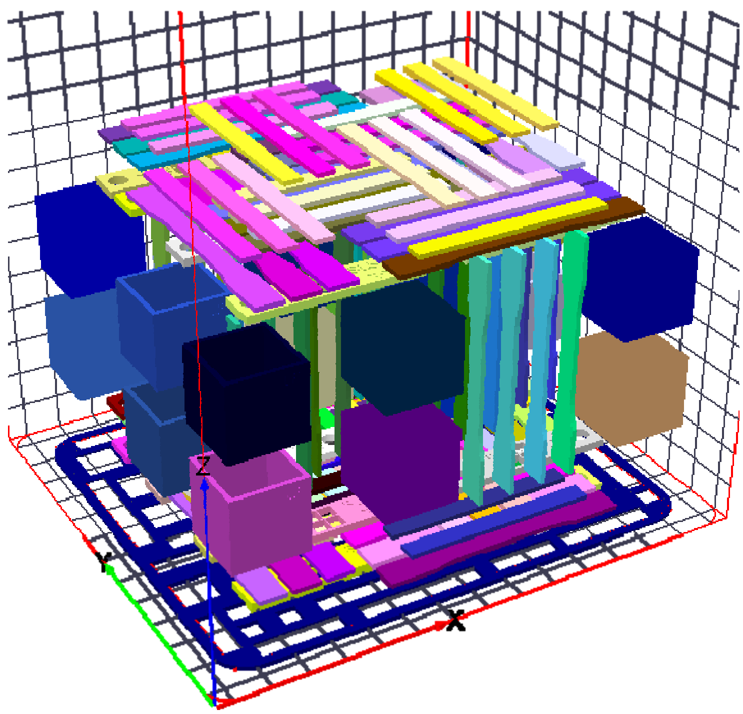


Figure 4.2: Sample Test Build for the DOE

The tensile dog bones were pulled on an Instron 3300 Tensile Tester to determine the modulus of elasticity. The density check pieces were thin rectangular pieces that were precisely measured in length, width and thickness, and then weighed to ascertain average density.

4.3 Material Selection

The ideal mechanical properties of the Nylon powders were discussed in the previous chapter. However, the actual mechanical properties can vary significantly based on both controllable variables (SS, SSP, LP) and the parameters that are more difficult to control (packing density, humidity, etc.). The achieved material properties for both powders are discussed below with their respective Andrew Numbers.

4.3.1 Nylon 12 Settings, Properties, Setup

The Nylon 12 DOE was completed first. The Andrew Numbers investigated were between 1.16 and 2.71 J/cm^2. The results show that density, in the area of investigation, is lightly related to AN, increasing with more energy input (Figure 4.3). The density, however, was still lower overall than expected. The theoretical density of Nylon 12 is 1.00 g/cc (see Table 1) and the best average density that was achieved was 0.91 g/cc. The Nylon 12 modulus results show similar light relation to AN, but with a severe drop off in the lower AN range (Figure 4.4).

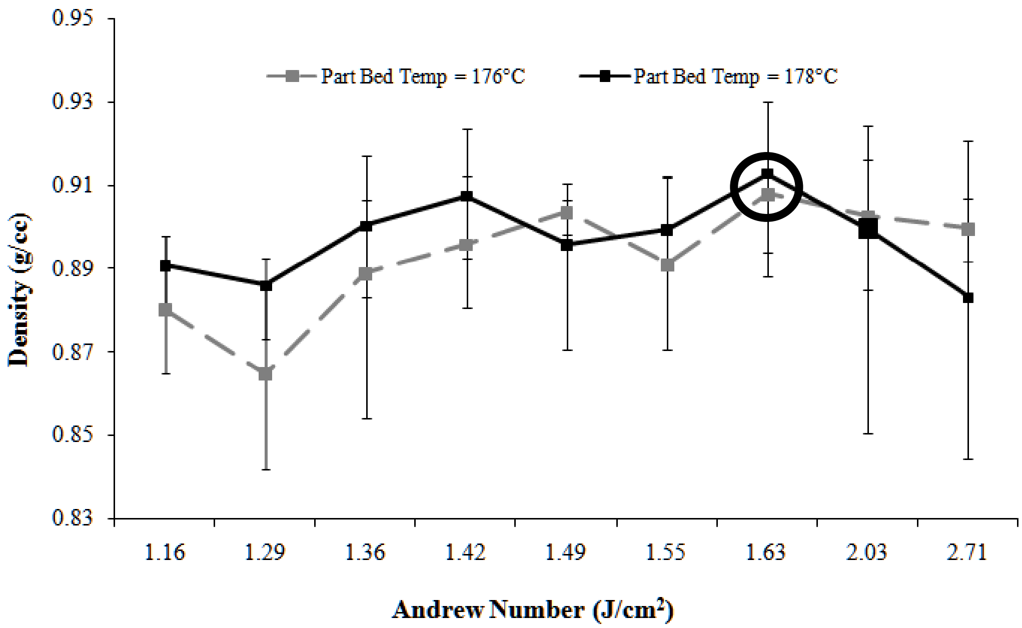


Figure 4.3: Nylon 12 Density vs. Andrew Number Results

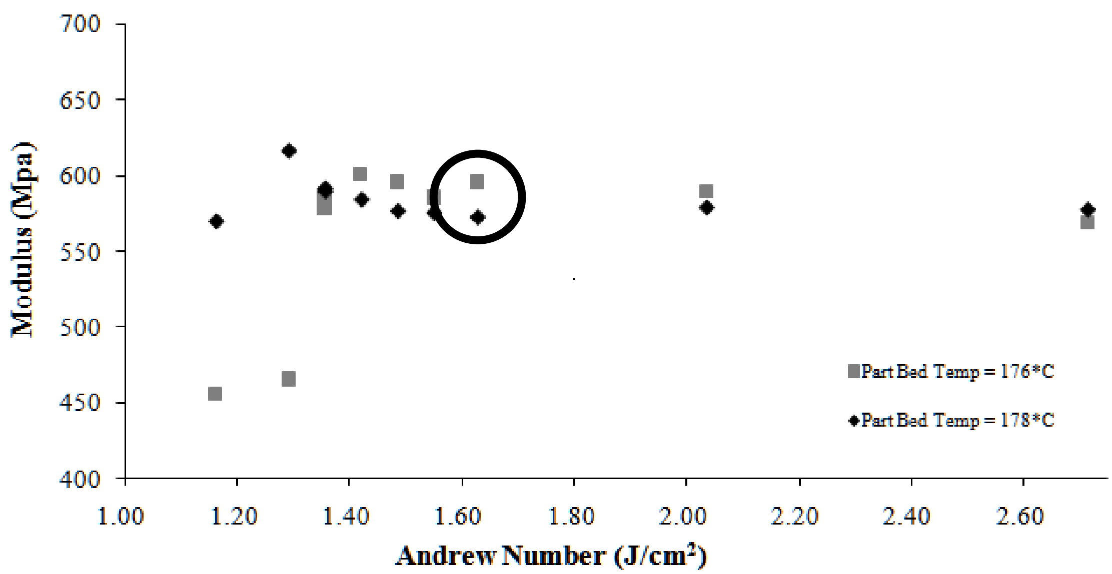


Figure 4.4: Nylon 12 Modulus of Elasticity vs. Andrew Number Results

Based on the results of both the density and modulus of elasticity tests, the selected optimal AN for Nylon 12 was 1.63 J/cm^2. The Nylon 11 results showed similar trends and the selected AN was 1.47 J/cm^2. For that AN, the density achieved was 0.971 g/cc (the ideal is 1.01 g/cc - Table 1). The modulus recorded for that AN was 209.94 ksi.

4.4 Experimental Setup & Methodology

The specimens were each attached to a test rig that included a pressure regulator for applying pressure, a pressure gauge for measuring applied pressure, and a dial indicator for measuring membrane deflection. A flow control valve was installed to insure consistent air supply and to prevent any accidental high pressure spikes that could cause membrane rupture. The complete test setup is shown below in Figure 4.5. Components were sized for connection with1/8" NPT pipe.

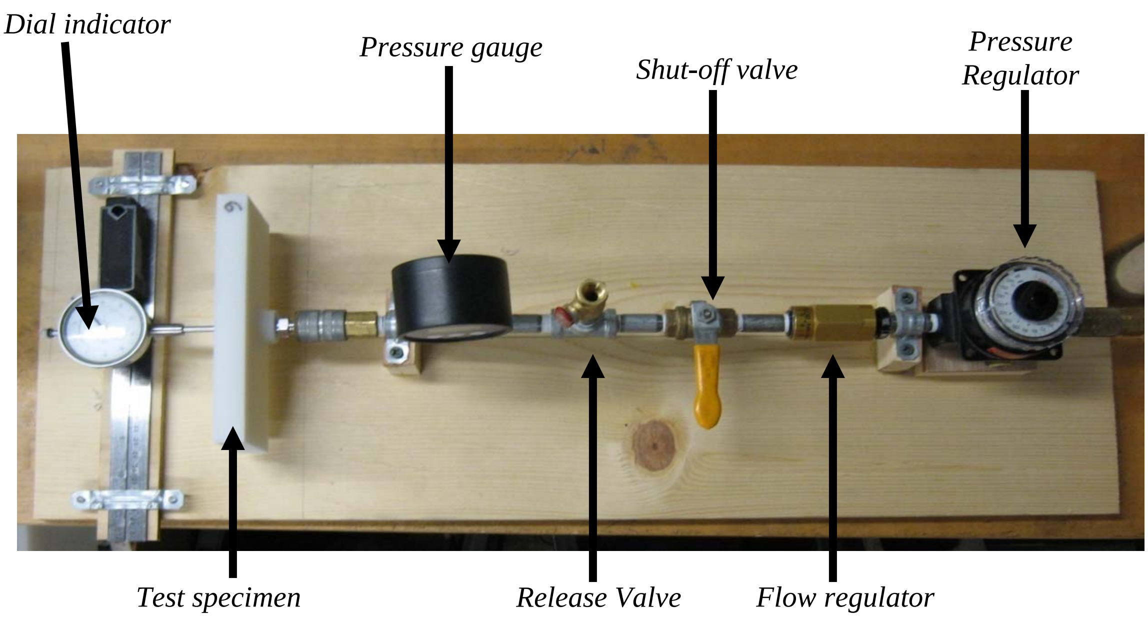


Figure 4.5: Experimental Test Setup

Complete Test Rig Component Specications:

- Wilkerson Dual-Air R21 Pressure regulator, range of 0 to 160 psig
- Mead Fluid Dynamics Dyla-Trol MF1-25 Flow control, varies from between 0 and 66 CFM
- Release ball valve
- Shut-off ball valve
- SSI Technologies MediaGauge™ MGA-9V Digital Pressure Gauge, 100 psi , accurate to +/- 1.0% Fullscale
- QuickConnect Pull-sleeve female pipe end
- Enco 0 to 1” Dial Indicator, accurate to 0.001”

The specimens were inflated using a shop compressed air line with a dehumidifier attached. Two test schemes were employed.

The first test was designed to evaluate plastic deformation. With this protocol, 5 psi was added incrementally, the deflection measured, and then the pressure was released. The residual deflection was measured before the sample was re-inflated to the pressure level achieved before release.

The second test protocol was designed to test deflection based on continuous inflation. Five psi was added incrementally until a maximum pressure was obtained. The deflection was recorded for each pressure increment. Once the final pressure was reached, the pressure was released. The residual deflection was then recorded.

4.5 Pressurization Results for Test Specimens

4.5.1 Flat Deflection Test Specimen

The next research task focused on characterizing the performance of each material at the selected build parameters. The material selected for the first build was Nylon 12, since there was more institutional knowledge at UT AUSTIN of its use and properties.

The Nylon 12 test specimens were built using ALM powder, a mixture of 50% virgin powder, 25% overflow and 25% part cake. All three sample thicknesses were built and tested (Figure 4.6). However, only one of the 1.0 mm thick membranes could be pressurized. The other two specimens of this thickness were too porous and could not be inflated. The high deflection recorded for the Nylon 12 flat specimens was 0.103 in at 32 psi.

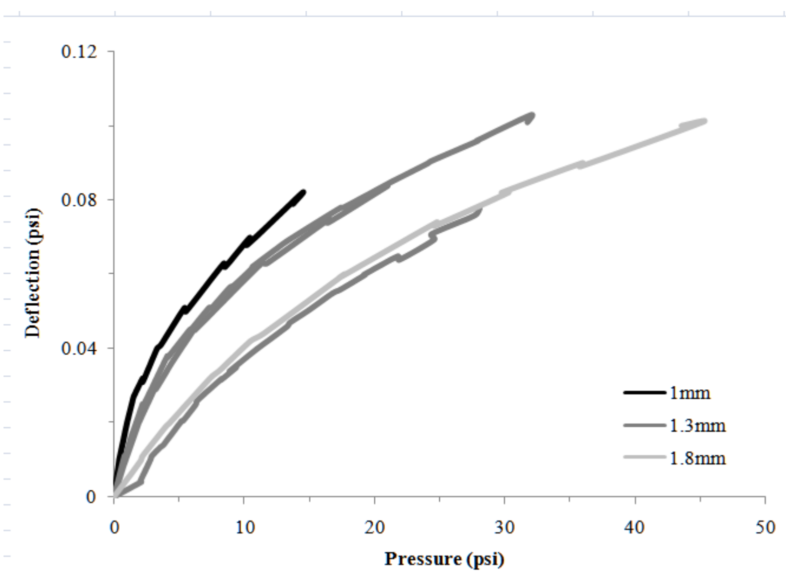


Figure 4.6: Flat Specimen Nylon 12 Inflation vs. Pressure Results

As Figure 4.6 indicates, one of the 1.3mm test specimens has a very different inflation curve. This aberration resulted from the test stand being disturbed and the dial gage being moved off of center. Since the inflated profile is round, the recorded displacement is lower.

The 1.0mm thick membranes experienced severe plastic deformation and the 1.3 mm thickness had minor plastic deformation (0.10 mm on average). The 1.8 mm thickness experienced no plastic deformation.

It became immediately obvious that the Nylon 12 specimens leaked (by different amounts) and would require application of sealant. A constant air supply was necessary for the test specimen to hold pressure. The Nylon 11 specimens held pressure to a much greater degree, but still leaked at high pressures, though at a significantly slower rate.

At this point, a comparison can be made between the experimental results and the predictions made by the theoretical equation and Finite Element Analysis (Figure 4.7). The original FEA completed with ideal material properties does not match at all with the experimental data.

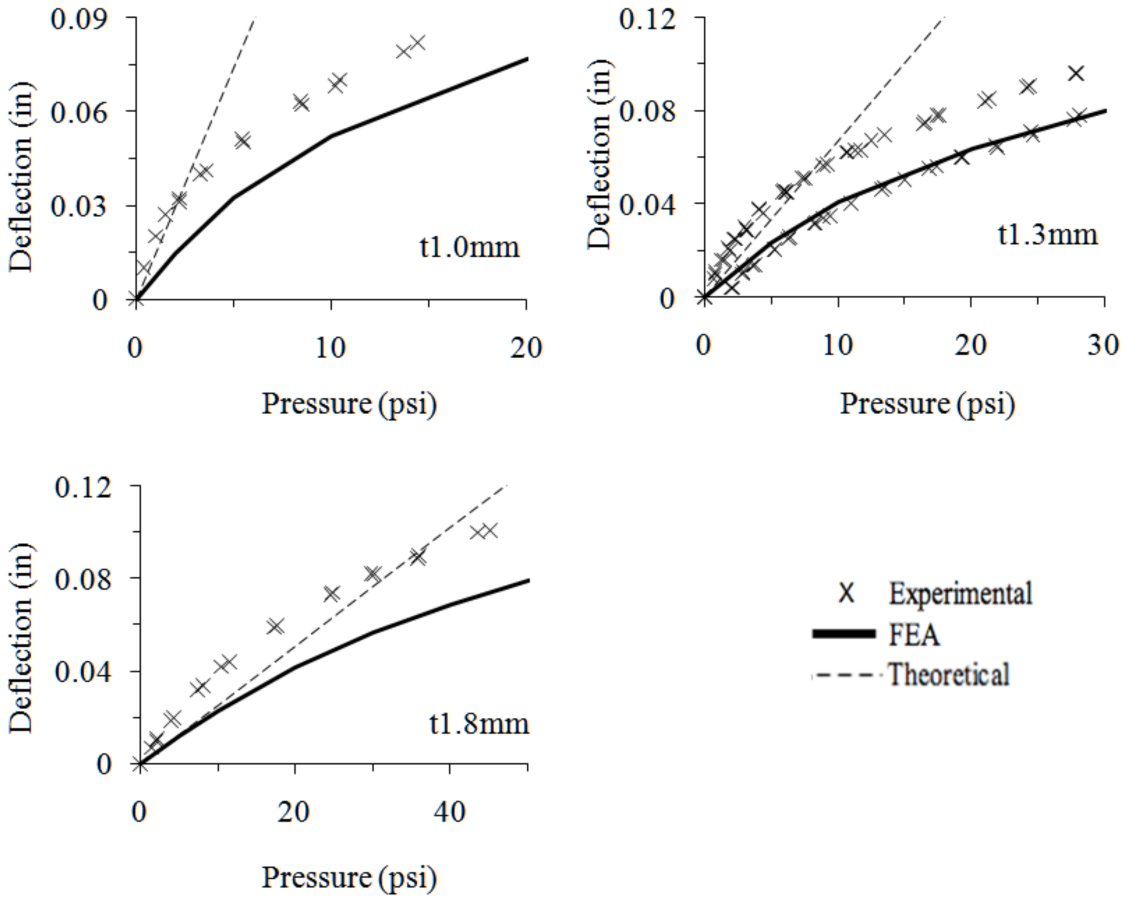


Figure 4.7: Deflection Pressure Curves for Nylon 12

The material properties of the actual parts are quite different from the nominal values (Table 1). The Young's modulus was determined experimentally through the theoretical equation—using low pressures—to be approximately 110,000 psi, far from the ideal of 188,000 psi. The FEA was rerun with the new material properties and the result is closer to the experimental data. The 1.3 mm thickness is shown below as an example of this improvement (Figure 4.8)

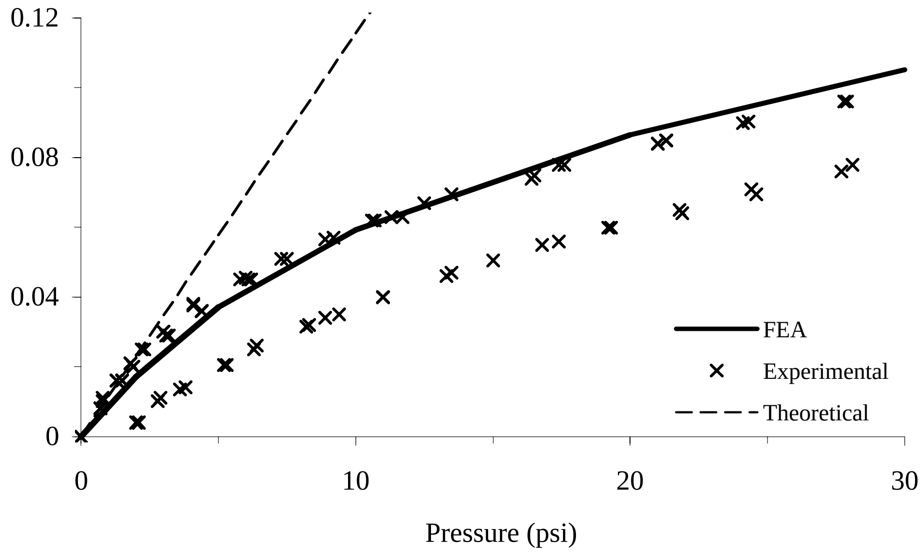


Figure 4.8: Predicted vs. Actual Deflection Pressure Curves for Nylon 12 t1.3mm.

The Nylon 11 test specimens were built using Arkema D80 Naturelle powder, 50% virgin, 50% overflow. Only the two thinner thicknesses (1.0 and 1.3mm) were built (Figure 4.9). Three samples were built of each thickness and inflated once. The maximum deflection achieved was 3.38 mm at 0.340 MPa on the 1.0mm thick membrane. Similar to the Nylon 12 specimens, the Nylon 11 specimens were very slow to return to original shape.

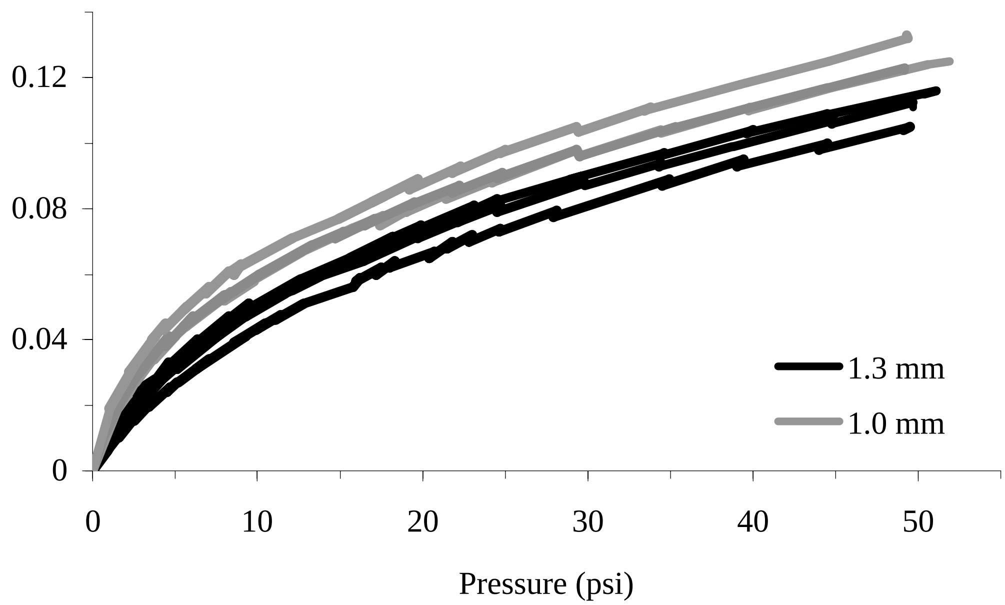


Figure 4.9: Flat Specimen Nylon 11 Inflation vs. Pressure Results

In contrast to the Nylon 12 results, the Nylon 11 experimental data is consistent with the FEA (Figure 4.10). Additionally, the low pressure data points match well with the theoretical equation. This agreement implies that the dimensions and the material properties align well with the ideal.

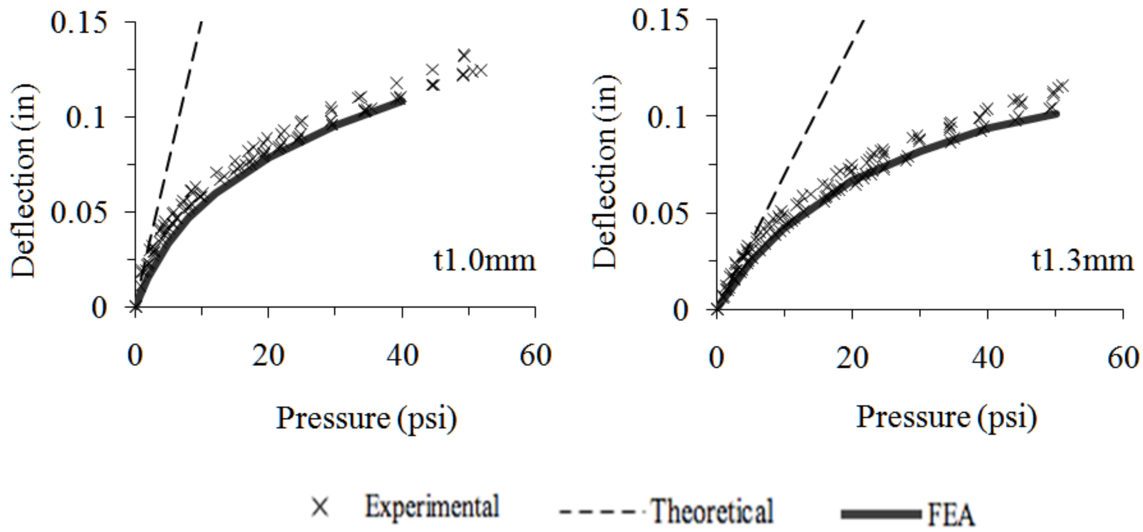


Figure 4.10: Deflection Pressure Curves for Nylon 11

4.5.2 Pressurization Results for Curved Test Specimens

The new curved specimens were built using Arkema Nylon 11 (D80 Naturelle, 50% virgin, 50% overflow), since that powder showed the best results in the previous test. Six identical specimens were built and tested using compressed air (Figure 4.11). The results at low levels of pressurization are markedly different. The range between 0 and 0.125 in of deflection showed rapid expansion as the initial concave shape popped out. Once the membrane popped out, the expansion from that point on is very similar to that observed earlier with the flat specimens. The maximum deflection achieved was 0.302 in with a pressure of 104 psi. Even at half-scale and with the same thickness the test piece exceeded the 6.1mm needed. However, 104 psi is a very high pressure and is unlikely to be actually used in practice. The actual working range necessary for the specimen is a much lower pressure range (0 to 6 psi, average), as highlighted in Figure 4.11.

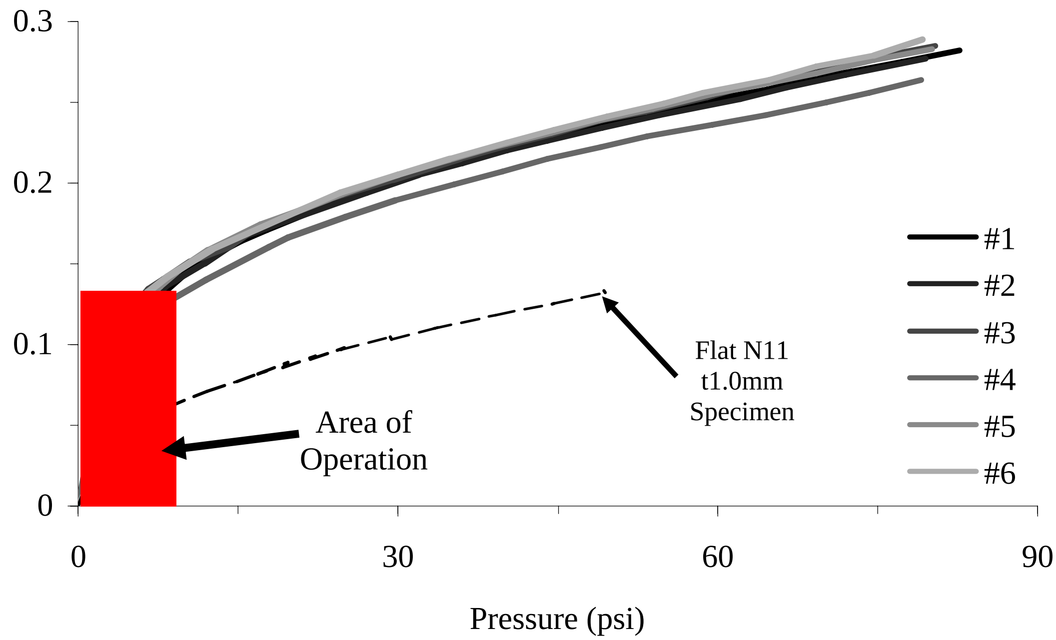


Figure 4.11: Curved Specimen Inflation vs. Pressure Results

The specimens were inflated to the maximum pressure and then all of the pressure was released. The specimens deflated to a convex shape that was nearly the inverse of the initial concave shape. The typical residual deflection was between 0.12 to 0.15 in. This deflection was not permanent, however, and the application of hand pressure snapped the membrane back to its original shape with negligible (less than 0.04 in) deflection. One specimen (#4) did not agree well with the others due to a disturbance to the test stand that moved the dial gage slightly off of center.

The FEA result was then compared to the experimental data. Unlike the flat test specimens, the results were inconsistent (Figure 4.12). The FEA differs by an order of magnitude. The analysis was revisited, but the material properties were accurate, as were the geometry matches between the model and the physical part. Further, these same material properties produced good results for the Nylon 11 flat pieces. It is possible that the disagreement is caused by the FEA program, COSMOSWorks. An ANSYS model should be developed to test this hypothesis.

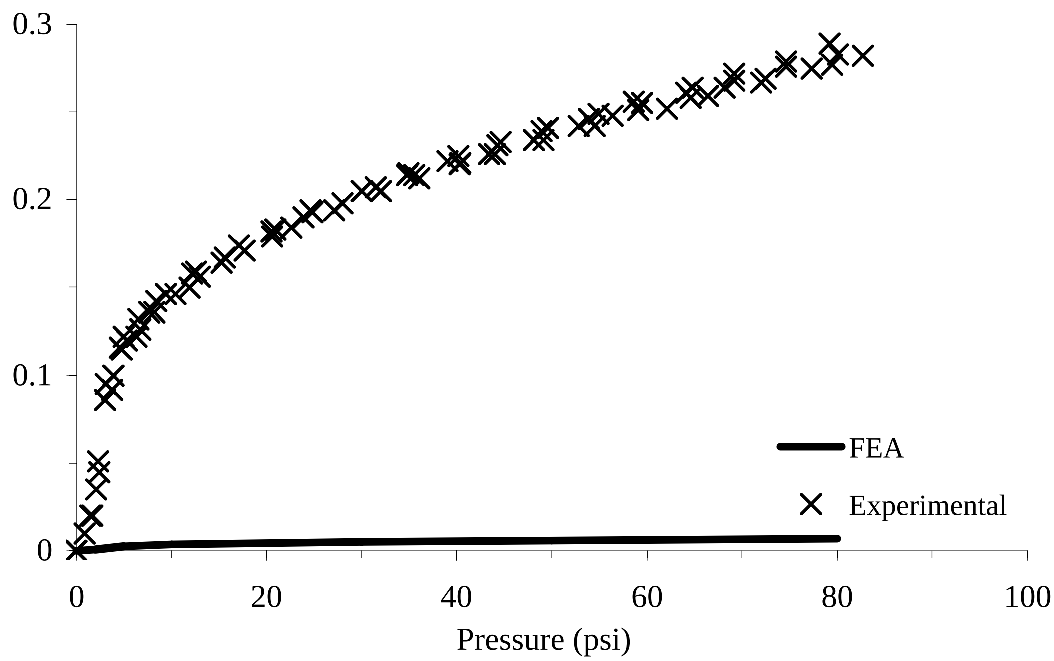


Figure 4.12: Comparison of Experimental Deflection of Curved Specimen to FEA

It is unusual, in light of the discrepancy with the order of deflection, that the general trend matches (Figure 4.13). There is hope that this FEA method may someday prove accurate.

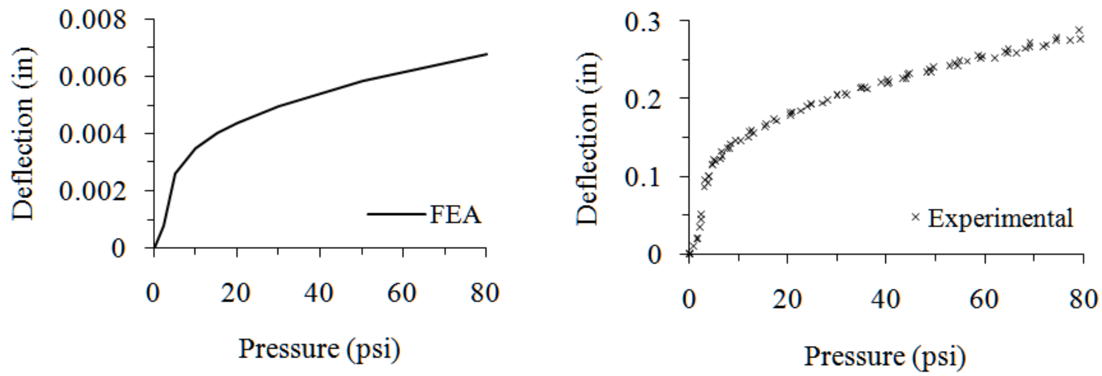


Figure 4.13: Comparison of Experimental Data and FEA for Curved Specimen

Since the results from the curved specimens were so promising, one specimen was selected and repeatedly inflated and deflated to test for plastic deformation or kinetic hardening (Figures 4.14 and 4.15). The results show that the material actually softens upon repeated cycling and takes less pressure to inflate in the low pressure range. Additionally, at high pressures, there is not a large decrease in maximum deflection. This test is preliminary and more sustained fatigue testing is needed before any such bladder could be used with confidence on a patient.

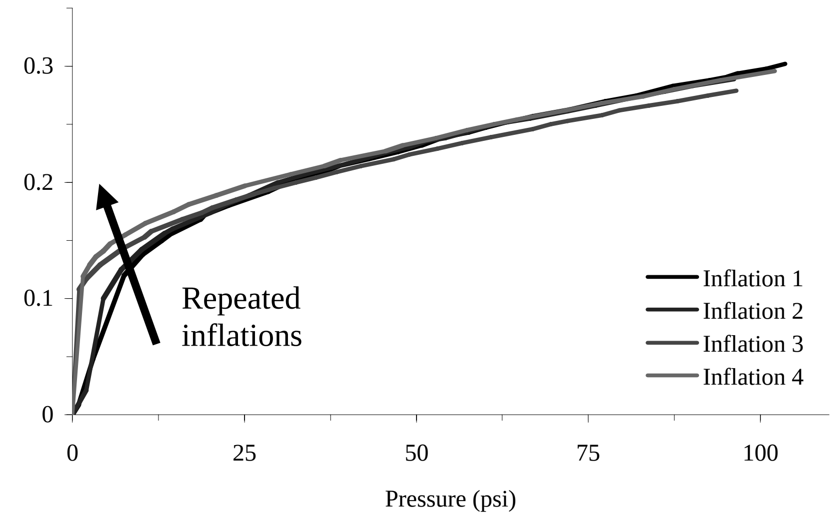


Figure 4.14: Repeated Inflation Cycling of Curved Specimen

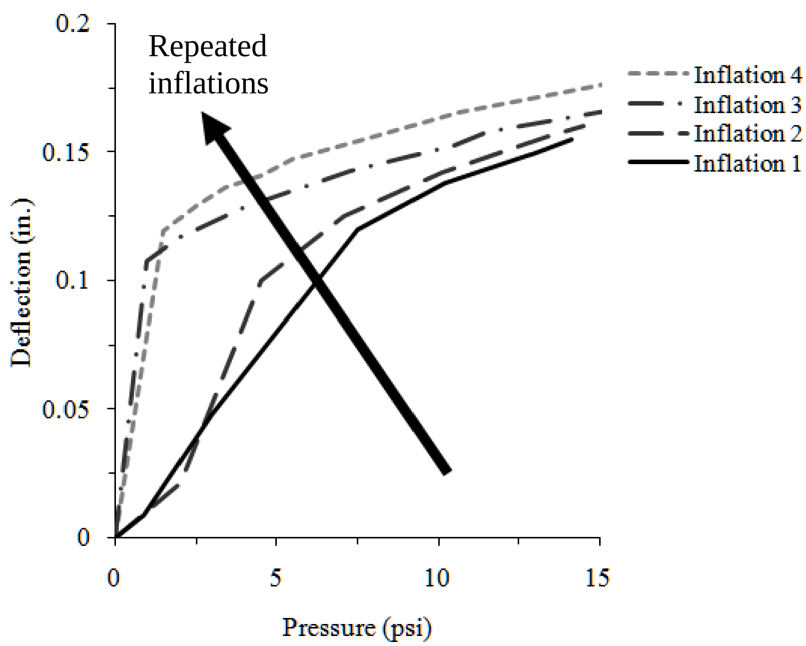


Figure 4.15: Repeated Inflation Cycling of Curved Specimen (Zoom)

Once these initial tests were completed for the 1.0 mm thickness test specimen, other specimens with different thicknesses were designed and built. Figure 4.16 shows a curve from a single test specimen deemed to be representative.

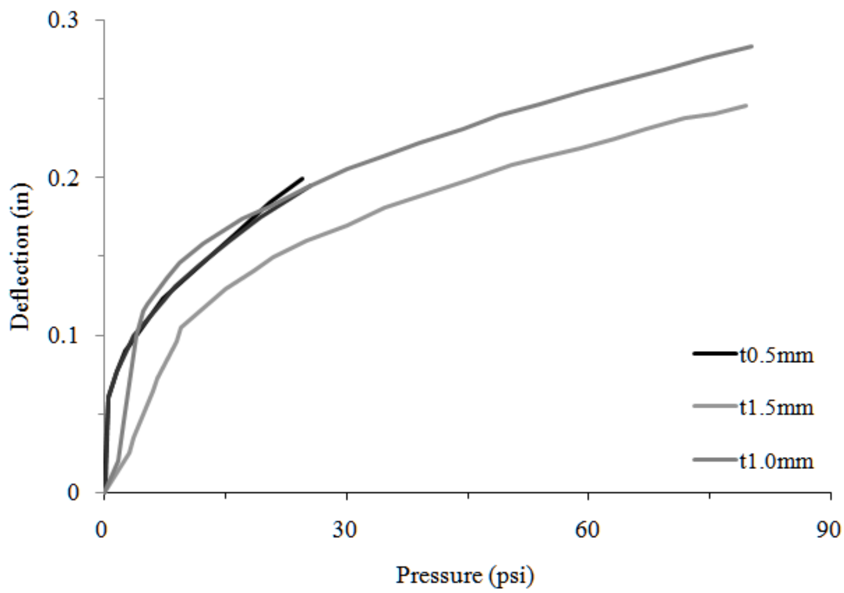


Figure 4.16: Representative Deflection Pressure Curves for Varying Thickness (Nylon 11)

The 0.5 mm thick membrane was very porous, and unable to hold any pressure. With a constant pressure source, however, a partial pressure deflection curve was still collected.

The curves of the new thicknesses have the two distinct stages of the original t1.0mm deflection curve, an initial stiffness associated with moving through the concave-convex area and the stiffer portion associated with stretching the convex shape outward. However, the thinnest membrane popped out into the convex shape immediately with the application of any pressure. The fact that other thicknesses show similar, but varied deflection curves will allow future work to have greater control over the pressure and deflection characteristics of the membrane.

4.6 Pressure Deflection Discussion

As previously discussed, the posterior distal tibia socket end of the residual limb requires the greatest deflection. A 6% volume change over a 4.29 in diameter region requires 0.24 in of deflection. When this example is scaled for the size of the test specimen, the required deflection is 0.112 inches. Because the largest deflection for either powder (0.103 in for Nylon 12 and 0.133 in for Nylon 11) cannot meet this specification with an acceptable actuation pressure, a flat plate single bladder will likely not suffice for this application.

The curved specimen results are very promising. The required deflection for the test case's size is 0.12 inches. This displacement is achieved easily since the maximum deflection measured was 0.302 inches at 104 psi. As an added benefit, the actual pressure range needed to achieve 0.12 inches is very small comparatively, 6 psi. The various thicknesses that are possible also increase the likelihood of developing a practical solution.

The control variables that will influence the final shape are laser power, scan spacing and part bed temperature for the SLS process, and thickness of the membrane and its concavity for geometrical variables. Between these five parameters it should be possible to fine-tune the desired pressure-deflection curve using the basic curved specimen template.

One final note is that while the material is flexible, it can still rupture. Several test specimens ruptured from one of two causes: either the pressure was too high (normally over 100 psi) or inflating too quickly to a high pressure (instant increase of 50+ psi). These incidents were rare and not expected, therefore no measurement was taken other than noting the approximate pressure at which the incident occurred.

4.7 Conclusion

The experimental work on this project has verified that SLS can create a part that can produce the anticipated deflection while maintaining the pressure requirements. The Design of Experiments was useful for not only selecting appropriate machine settings, but providing a thorough understanding of the complexity involved with an SLS system. The difficulty of the SLS process is the complexity and sheer number of variables that determine a successful build. But the trained and experienced user should be able to turn this potentially overwhelming number of variables into a high level of control for a highly accurate part.

The material properties for the test specimens resulted in successful part performance, but have also been reproducible since selection. The flat test specimens were inadequate, but the lessons learned informed the design of the curved test specimen that was much more successful. The Finite Element Analysis completed so far has been encouraging, producing good results for the flat test specimens. Further development should improve the accuracy of the curved specimen FEA.

Chapter 5

CONCLUSIONS

Overall conclusions are presented in this chapter with a discussion of possible sources of error and areas available for improvement. Additionally, recommendations for future work are provided, both for the short-term continuation of membrane development and for long-term development of the total socket and potential actuation methods.

5.1 Conclusions

By now it has been well-established that there exists a need within the prosthetics market for an actively actuated below-knee socket. Existing solutions do not meet patient needs for comfort and fit, due to unaddressed changes in limb volume. Poor fit can adversely affect gait and can cause any number of health problems.

The developed concepts meet the specific requirements of the patient in a broad number of methods. The inflation-based designs, as well as the others developed and enumerated upon in Appendix A, leverage the power and simplicity that the Selective Laser Sintering (SLS) manufacturing method provides, namely customization and integrated part design. Two small test specimens were developed to determine pressure and deflection characteristics for two SLS materials, Nylon 11 and 12. The first test specimen used a flat circular membrane. The second test specimen used a circular membrane as well, but included built-in concavity to simulate the contour of an actual socket.

The Design of Experiments (DOE) to determine SLS processing parameters led to usable and reliable build settings. These settings have been in use for nearly a year with little change. These settings are unique to the machine in use by UT Austin. The protocol developed to explore and evaluate machine settings for various mechanical properties is universal. Additionally, if the HiQ Sinterstation used in this experimental work undergoes any upgrades in the future, it will be necessary to revisit or even reevaluate the selected machine parameters.

Currently, the flat test specimens lack the necessary deflection range and require too much pressure to actuate. The redesigned curved specimen, however, shows promise in both of these areas. The softening of the material from repeated cycling makes the expected performance of the specimens even more appealing.

The finite element analysis of the flat test pieces has shown strong correlations to the experimental results. And, while the flat test pieces do not bear direct use for the total socket, they are exceedingly helpful in verifying that the finite element analysis is appropriate and has accurate mechanical properties. Agreement in these early simpler tests will provide the confidence needed as the size and shape of test specimens increases in complexity in the future.

5.2 Selective Laser Sintering Variance and Recommendations

The machine settings resulting from the DOE have produced good quality parts for some time now. However, there are some parameters that are either not controllable through the build computer or that are poorly understood. These variables are temperature variance as a function of position in the build (X, Y and Z) and humidity. Position in the build has been researched generally (Silverman, 2007), but the effects that it causes on mechanical properties has been less thoroughly documented. It is impossible to create a completely uniform temperature on the build chamber surface within the heated part chamber. The temperature is largely uniform across the central area with variances of a few degrees randomly, but the temperature consistently drops off near the edges. The temperature variance can result in variances in density and other properties. Also, there are temperature gradients across the height of the build. The higher the build, the more heat accumulates throughout the build. Heat variances in the SLS process, more than other manufacturing methods, results in property variance.

The effect of build location of the test specimens was largely neglected, not for the effect that it has, but rather the lack of control of the temperature. The only considerations with regard to build location were to keep the parts away from the edges and to keep the builds as short as possible.

SLS, as with any manufacturing process, does not always create a perfect part and orientation within the build can affect fine details or curl. A membrane built facing downward will have different properties than one built facing sideways. Examples include striations and stair stepping along curves. The experimental work at this point focused on consistency in build orientation for comparison between other factors. It is obvious that in a full-scale socket, the bladders will be fabricated in a variety of locations. It is recommended that for the immediate future the membranes be built in a consistent layout. Once the other parameters are well understood, the role of part orientation should be explored.

One last factor is the humidity in the lab where the SLS machine is located. Humidity can affect the builds because the powder is so fine that it can trap water vapor. The accumulated water vapor changes the thermal properties of the powder and ultimately the mechanical properties. A humidity sensor has recently been installed so that when the effects of humidity are studied, there will be historical data to reference.

While the Nylon 11 test specimens did not require a sealant to maintain pressure, the final socket will require some kind of seal both to provide appropriate surface finish for a consumer product as well as to guarantee that the socket remains sealed during its entire life. The surface finish for a consumer product will place requirements on smoothness and wear that are not necessary at this stage of the design process.

5.3 Experimental Data Collection Error and Recommendations

The pressure deflection data up to this point has been focused on characterizing the test specimens over a wide range in order to establish general behavior. The pressure regulator used has a selectable resolution of approximately 2.5 psi and has an upper limit of 160 psi. Now that the required pressure range has been established (approximately 10 psi for the curved specimen), it is recommended that the regulator be replaced with one with a smaller range and a greater sensitivity for future work. A general recommendation would be at most 25 psi maximum and at most a 1 psi resolution.

In the area of experimental data collection, two samples were discarded due to experimenter error. A nudge or a bump meant that the dial indicator shifted and the deflection measured was no longer consistent. The sample could not be re-measured because of the softening that occurs with each subsequent deflection. The experimentation was conducted on a lab table in the SLS lab. It is recommended that in the future all tests be conducted with the test stand clamped to the table.

Finally, the test setup is rather large such that the volume of the test specimen is dwarfed by the volume of air in the test apparatus. The compressibility of air and the large volume of air created time variances in the data. It could take quite a long time for a pressure reading to stabilize, even if the deflection change had ceased earlier. At first, this effect was thought to be an aberration caused by the digital pressure sensor, but the same effect was noticed with a pressure transducer attached to a voltmeter. This instability is acceptable for the static tests undertaken so far, but it does prevent any dynamic pressure-deflection measurement. While revisions to the test rig have already decreased the non-test specimen volume, it is recommended that future experimenters bear this phenomenon in mind.

5.4 Future Work

Immediate future work on the inflatable prosthetic socket concept should include a full-scale test specimen of the prosthetist's recommended case. Additional work on the Nylon 11 test specimens will need to be undertaken to deepen the understanding of thickness on deflection, but also to evaluate different membrane sizes—for other diameters as well as non-circular membranes.

Once individual membranes can be designed with confidence, they will need to be integrated into an overall socket before subject trials can begin. The design and experimental work thus far can be applied to a socket with either localized pressure relief or one of the global deflections discussed in Chapter 3. This project has focused on global volume management, but localized and independent bladders in a total socket could provide a less complicated test platform for developing the actuation systems.

The actuation method needs to be studied for functional feasibility. The simplest inflation method is pneumatic, with a piston as a pressure source. The primary variable to control will be volume, which can be difficult since it is not an independent variable. The following parameters need to be studied and evaluated: applied pressure from the patient onto the socket, required pressure for maintaining a set volume, the force and work required to achieve volume changes. The first test scenario will evaluate what can be achieved through a single gait cycle. After the completion of this testing scenario, whole day and extended volume changes can be studied. Once overall feasibility has been determined an actual design can embodied that includes the piston, valves and any necessary tubing.

Initially, the actuation system will need further feasibility studies, particularly regarding time profiles of socket-limb pressure and volume changes. It is also recommended that the inflation media options be expanded to include water. Once the media and time response characteristics are established, the design of the control system can begin. The control system will need to be automated and based on a thorough model of the socket's inflation. A socket can then be built with inflation and a control system for initial testing.

As all these areas are developed, pilot studies and subject trials can begin.

Appendix A

VOLUME ACTUATION CONCEPTS

A.1. Inflation Concepts

These concepts use “inflation” as their key design method. They all utilize a still outer shell and a flexible inner membrane. The inner membrane takes a variety of forms,

Concept 1: Inflating Plates

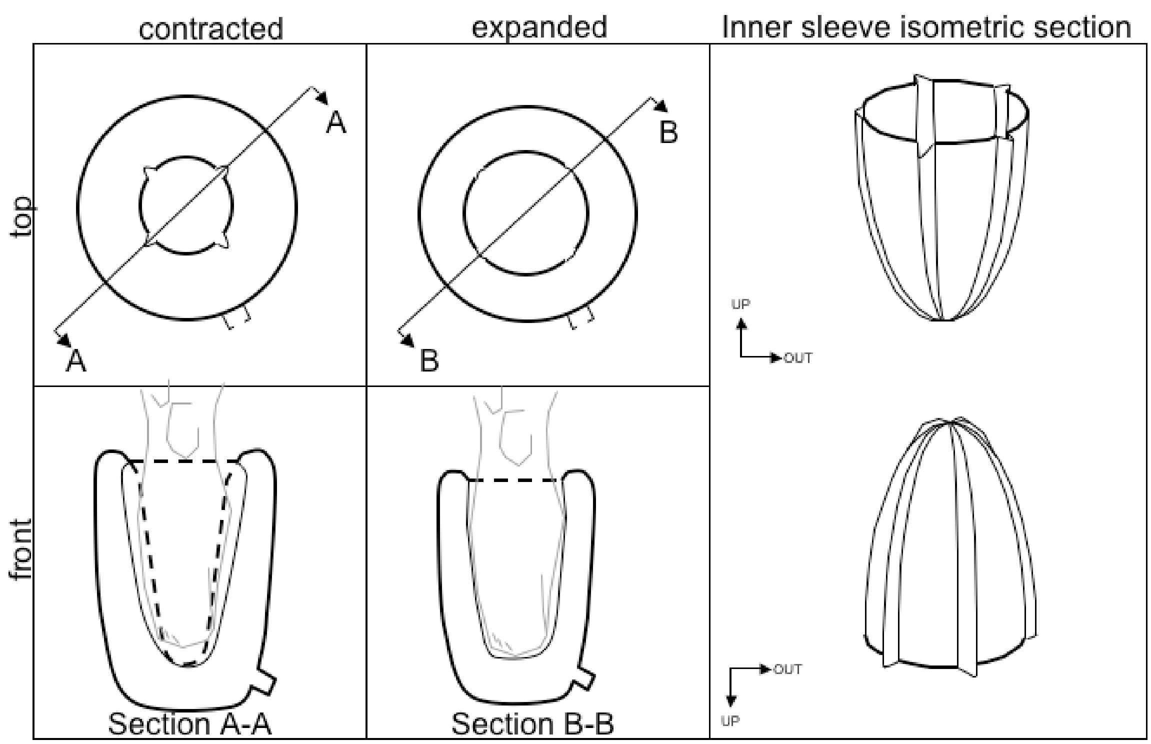


Figure A.1: Inflating Plates Concept views

Description:

An inner sleeve of stiff plates and thin flexible membranes expands and contracts to match the shape of the remnant limb. The native shape is smaller than the remnant limb, then a vacuum is drawn on the inner portion to expand its shape. This expansion allows for insertion of the limb. The degree of vacuum pressure drawn determines the shape the inner sleeve takes. The stiff sections allow for good force transmittal while the thinner sections allow for shape changes.

Pro's

- Stiff sections allow for local pressure relief to be incorporated
- Plates allow for more confidence in shape that expanded sleeve will take.

Con's

- Failure of pump will contract socket too much and crush residual limb (!)
- Free movement (limb can swing)

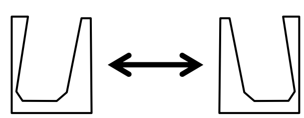


Figure A.2: Possible Movement of Limb within Socket

- Addition of rigid plates will create localized pressure hotspots as seen in traditional non-adaptive sockets
- Flexible sections are susceptible to fatigue (high strain and flexure)
- Area near flexible sections susceptible to cracking

- Contracting plates can pinch skin
- Assumes linear and uniform swelling of limb (can create line or point contact if not properly aligned)

Plate and Membrane design parameters:

- Size & spacing
- Number
- Stiffness
- Orientation
- Secondary design parameter: amount of pressure needed

Outer Shell design parameters

- Size
- Gap between inner and outer shells
- Expanded vs. contracted
- Location of pump tap

Concept 2: Multiple Independent Membranes

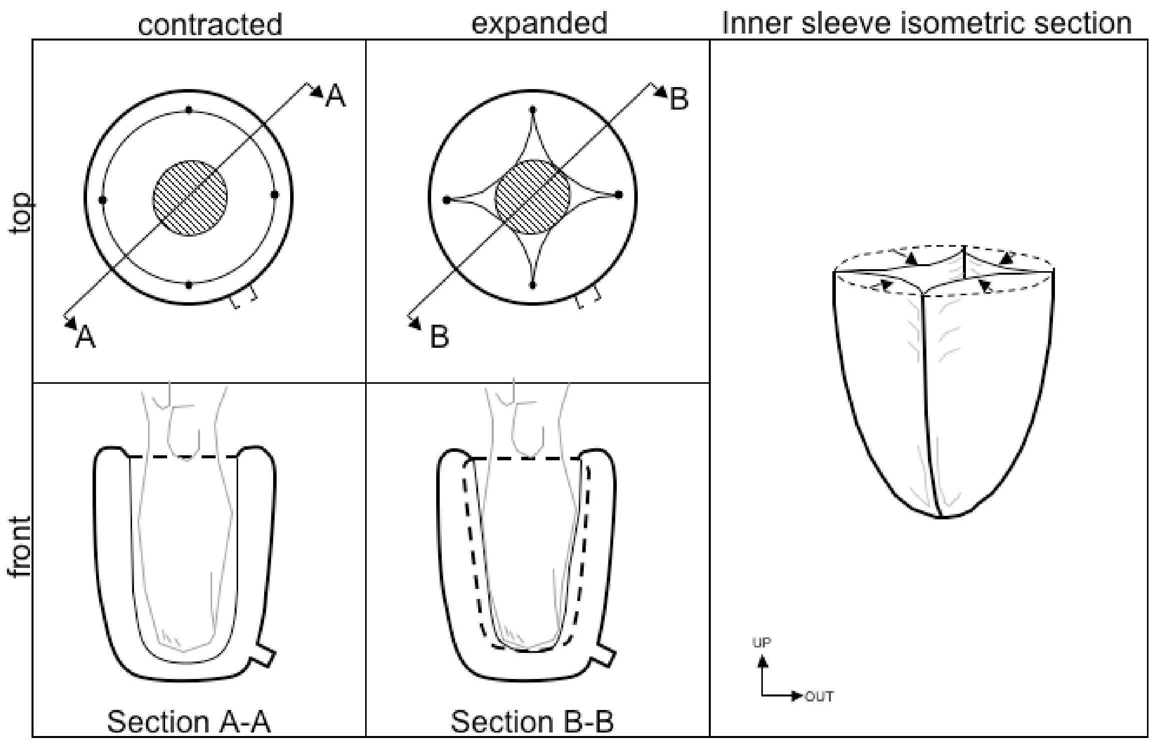


Figure A.3: Multiple Dependent Bladders Concept Views

Description:

An inner sleeve of flexible membranes is inflated to expand and conform to the shape of the remnant limb. The membranes are joined at stiff ribs which will allow for varying non-uniform shapes. All of the membranes share the same pressure source. The amount of expansion is determined by pressure applied.

Pro’s

- Inflated shape more reasonable to theoretically determine than other designs
- Fail state is safe for user
- Pressure input can be located inside the pylon
- Not likely to pinch skin

Con’s

- Free movement (limb can swing, Figure A.2)
- Can create pressure hotspots from non-uniform contact (particularly with over-inflation)

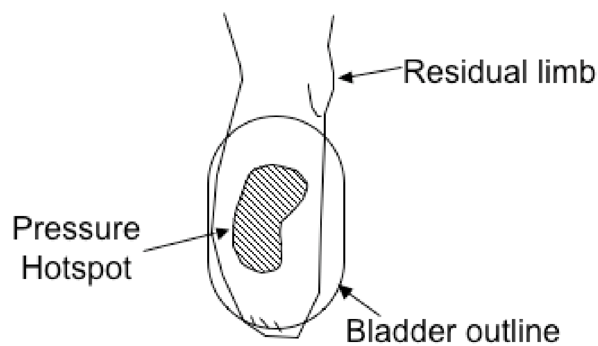


Figure A.4: Possible Pressure Hotspots on Residual Limb

- Areas near ribs are susceptible to fatigue
- Area farthest from the ribs will see high strain

Membrane Design Parameters:

- Size & spacing
- Number

- Stiffness
- Orientation
- Amount of contact with residual limb
- Secondary design parameter: amount of pressure needed

Outer Shell Design Parameters

- Size
- Gap between inner and outer shells
    - Expanded vs. contracted
- Location of pump tap
- Should bottom of the sleeves connect or not?

Concept 3: Multiple Independent Bladders

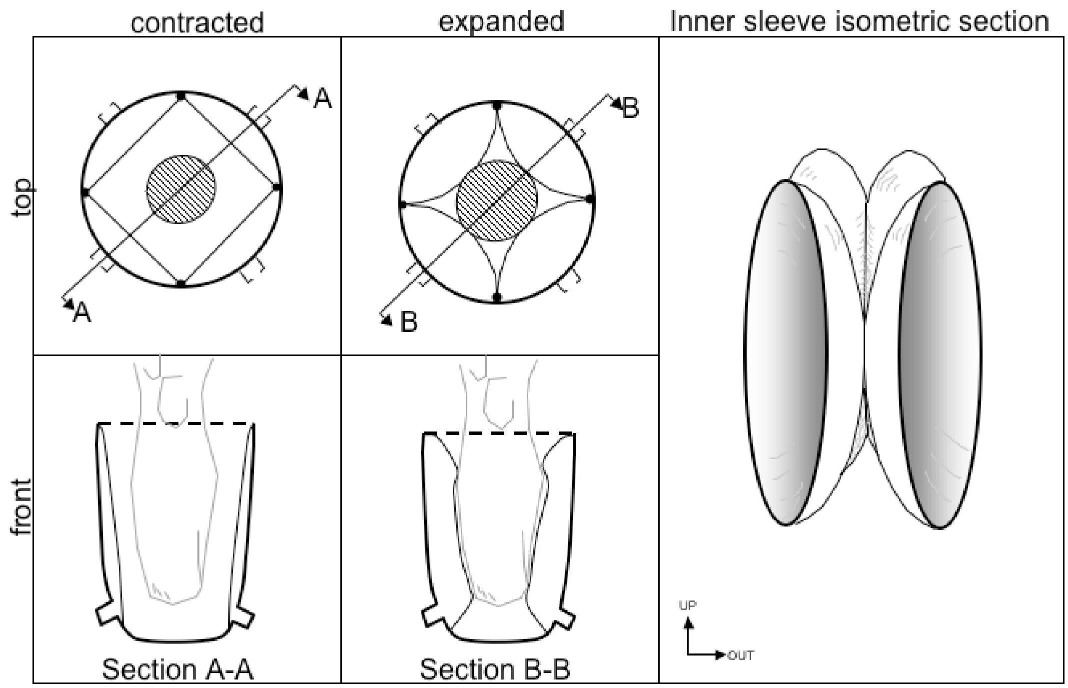


Figure A.5: Multiple Independent Bladders Concept Views

Description:

Multiple independent bladders are inflated to conform to the shape of the residual limb. Each bladder has its own pressure control. The system will allow for much greater control, but at the cost of greater complexity.

Pro's

- Much greater level of control (is this level needed, though?)
- Inflated shape more reasonable to theoretically determine than other designs
- Fail state is safe for user

- Not likely to pinch skin

Con’s

- Complex in control
- Complex in application (N# of valves, nozzles, lines, etc.)
- Outer surface will need to be designed to hide pressure hookups (for smooth shape)
- Free movement (limb can swing, Figure A.2)
- Can create pressure hotspots from non-uniform contact (particularly with over-inflation, Figure A.4)
- Areas near ribs are susceptible to fatigue
- Area farthest from the ribs will see high strains

Membrane Design Parameters

- Size & spacing
- Number
- Stiffness
- Orientation
- Amount of contact with residual limb
- Secondary design parameter: amount of pressure needed

Outer Shell Design Parameters

- Size
- Gap between inner and outer shells
  - Expanded vs. contracted
- Location of pump taps
- Should bottom of the sleeves connect or not?

Concept 4: Single Global Bladder

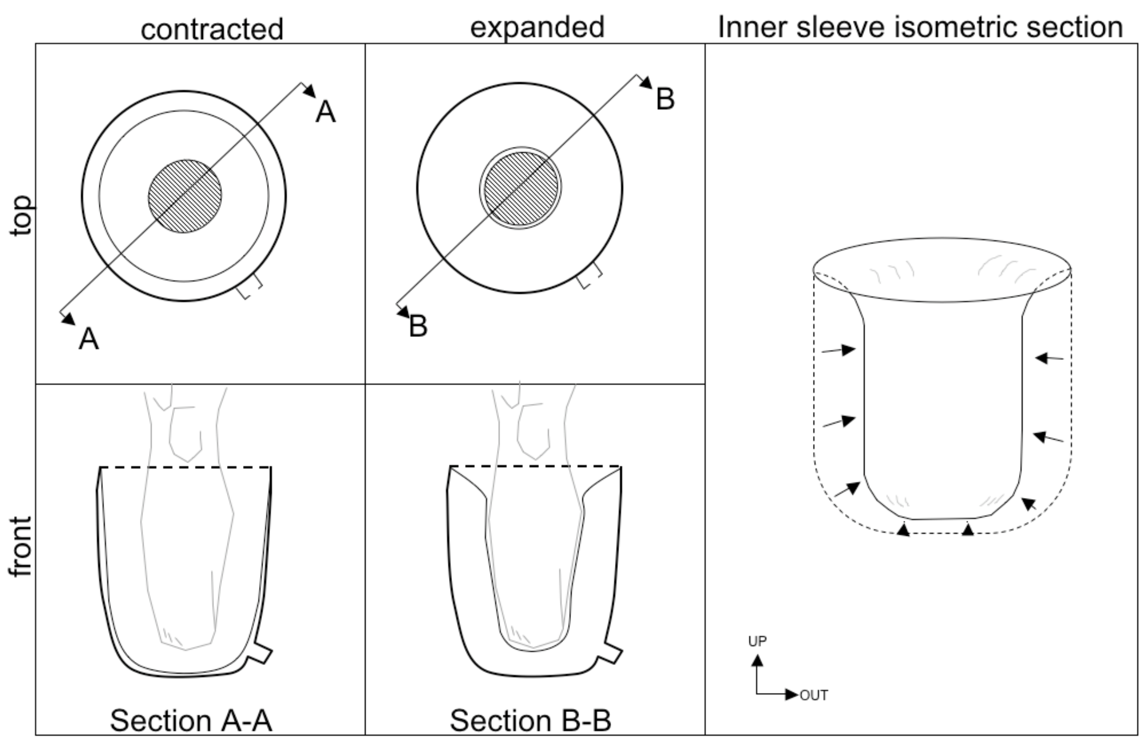


Figure A.6: Single Global Bladder Concept views

Description:

One flexible membrane that inflates organically to conform to the remnant limb.

Pro’s

- Best potential for total surface contact.
- Simplest implementation (fewest components/ design parameters)
- Fail state is safe for user
- Not likely to pinch skin

Con’s

- Little control over shape
- Expanded shape is difficult to determine theoretically.
- Free movement (limb can swing, Figure A.2)
- Can create pressure hotspots from non-uniform contact (particularly with over-inflation, Figure A.4)
- If membrane isn’t flexible enough, then it can create line or worse point contact on the limb.
- Areas near ribs are susceptible to fatigue
- Area farthest from the ribs will see high strains

Membrane Design Parameters:

- Stiffness
- Secondary design parameter: amount of pressure needed

Outer Shell Design Parameters:

- Size
- Gap between inner and outer shells
- Expanded vs. contracted
- Location of pump tap
- Should bottom of the sleeves connect or not?

A.2 Non-Inflating Concepts

These concepts use other methods of volume actuation, most of which are mechanical, but one that uses a non-SLSed bladder that would be manufactured separately. The mechanical designs draw inspiration from tool and pipe examples.

Concept 5: Insertable Bladders

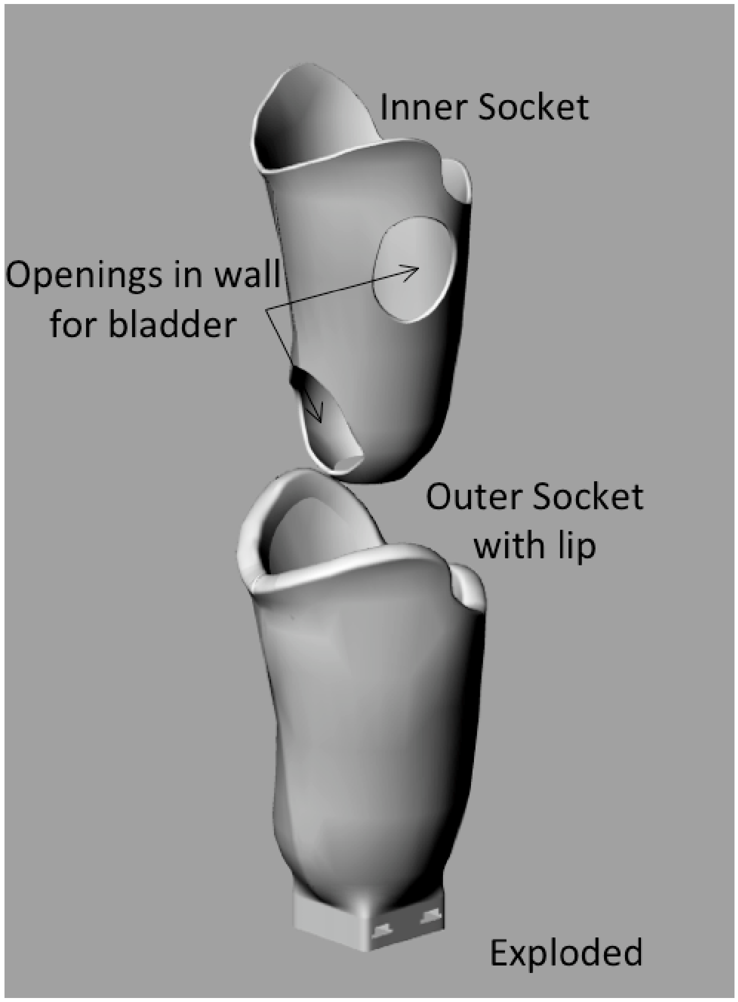


Figure A.7: Exploded View of Insertable Bladder Concept

Description

Either multiple small bladders that can adhere to an existing socket wall design or a single large bladder sandwiched between an inner and outer socket.

Concept 6: Rotary Spring Analogy

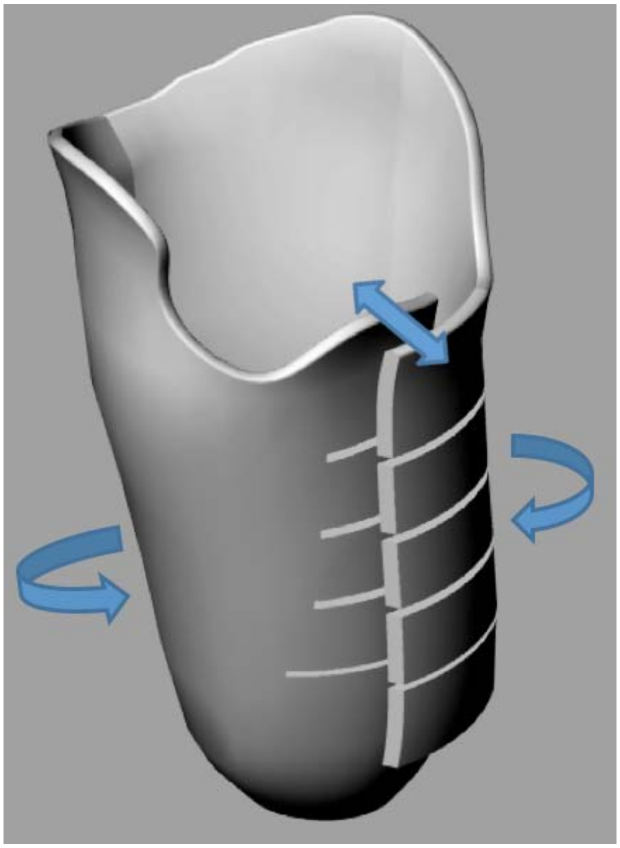
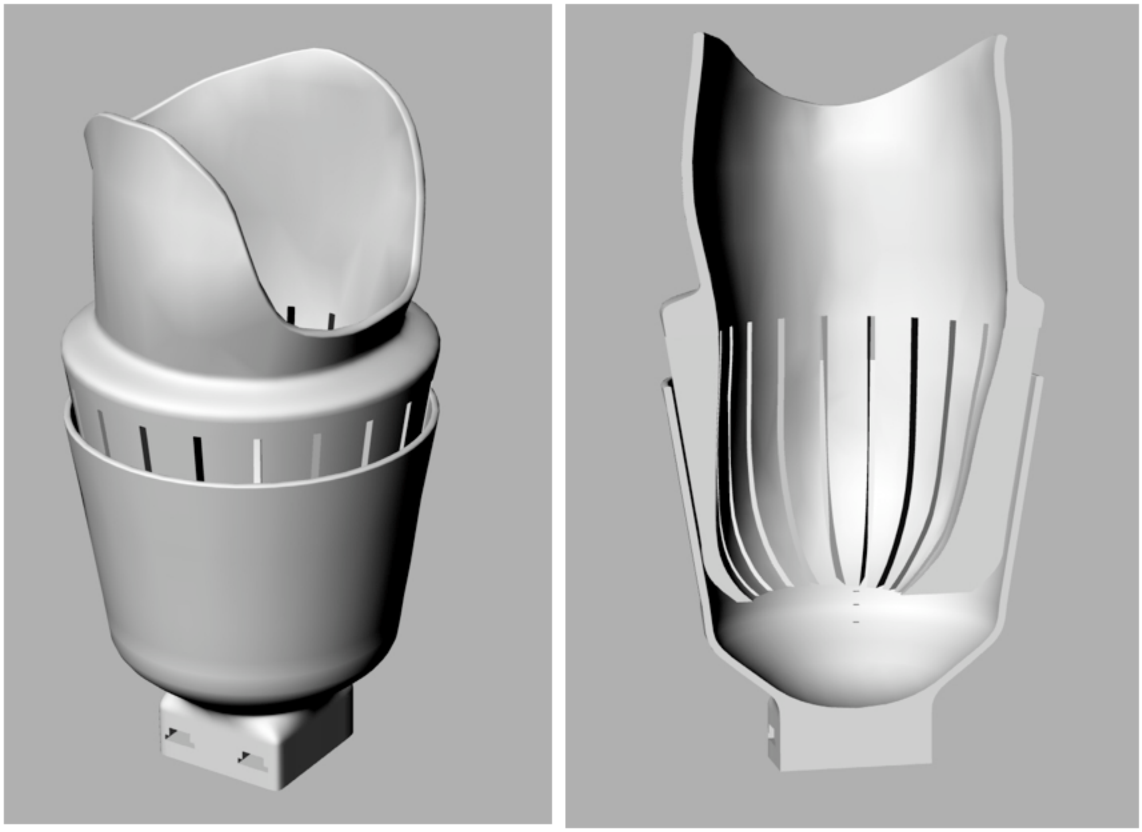


Figure A.8: Rotary Spring Concept

Description

Compression of the springs reduces the available socket volume.

Concept 7: Collet Analogy



(a) (b)

Figure A.9: Collet Concept Isometric View (a) and Section View (b)

Description:

This concept uses an analogy to a drill press tool bit collet. Volume change is achieved by sliding the upper part up and down the outer shell. Higher in the shell corresponds to larger volumes, and the flanges compress as the shell's diameter diminishes.

Concept 8: Pipe Clamp Analogy

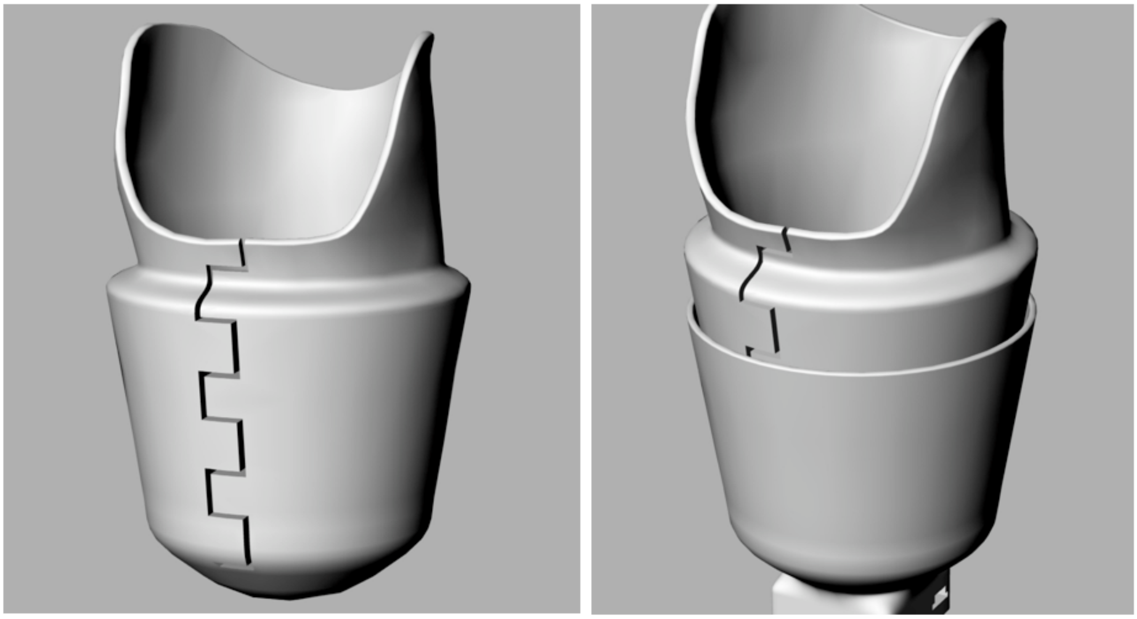


Figure A.10: Pipe Clamp Concept Views

Description:

This concept uses an analogy to a pipe clamp. Volume change is achieved by sliding the upper part up and down the outer shell. Higher in the shell corresponds to larger volumes, and the clamp compresses as the shell's diameter diminishes.

Bibliography

Bhagwat, Lokhande Mahendra. "Design of a Compliance Model for a Prosthetic Socket Fabricated Using Selective Laser Sintering." MS thesis. U of Texas at Austin, 2001. PDF file.

Biel, Tracy L, and Glenn M Street. "Comparison of interface pressures with pin and suction systems." *Journal of Rehabilitation Research & Development* 41.6A (2004): 821-828. *JRRD*. Web. 2 Nov. 2009. <doi: 10//.2003.09.0146>.

Bosker, Gordon. Personal interview. 23 Sept. 2008.

CES Edupack. 2009 ed. Vers. 5.1.0. Rel. 2009,2,27,1. Cambridge: Granta, 2008. CD-ROM.

Deckard, C.R. "Part Generation by Layerwise Selective Sintering," MS Thesis. U of Texas at Austin, 1986

Deckard, C.R. "Selective Laser Sintering" Diss. U of Texas at Austin, 1988

Dillingham, Timothy R, et al. "Use and Satisfaction with Prosthetic Devices Among Persons with Trauma-Related Amputations: A Long-Term Study." *American Journal of Physical Medicine & Rehabilitation* 80.8 (2001): 563-571. Print.

Enderle, John D, Susan M. Blanchard, and Joseph D Brozino. *Introduction to Biomedical Engineering*. 2nd ed. Amsterdam: Elsevier Academic Press, 2005. Print.

Faustini, Mario Carneiro. "Modeling and Fabrication of Prostheses Using Selective Laser Sintering." Diss. U of Texas at Austin, 2004. PDF file.

Fernie, Geoff R, and Pamela J Holliday. “Volume Fluctuations in the Residual Limbs of Lower Limb Amputees.” *Archives of Physical Medicine and Rehabilitation* 63 (Apr. 1982): 162-165. Print.

Freeman, Donald, and Leslie Wontorcik. “Stereolithography and Prosthetic Test Socket Manufacture: A Cost/Analysis.” *Journal of Prosthetics and Orthotics* 10.1 (1998): 17-20. *American Academy of Orthotists & Prosthetists*. Web. 2 Nov. 2009. <http://www.oandp.org///_01_017.asp>.

Greenwald RM, 2003, “Volume Management: Smart Variable Geometry Socket Technology for Lower-Limb Prostheses,” Journal of Prosthetics Orthotics International, 15(3), pp. 107-112.

Goh, JCH, PVS Lee, and S Y Chong. “Stump/Pressure Profiles of The Pressure Cast Prosthetic Socket.” *Clinical Biomechanics* 18.2 (2003): 237-243. *Science Direct*. Web. 2 Nov. 2009. <doi:10.1016/.physletb.2003.10.071>.

Gosthnian, Barry M, and Hugh Herr. Inflatable Limb Prosthesis with Preformed Inner Surface. Patent 4,923,475. 8 May 1990. N.p., n.d. Web. 2 Nov. 2009.

Legro, Marcia W, et al. “Issues of Importance Reported by Persons with Lower Limb Amputations and Prostheses.” *Journal of Rehabilitation Research & Development* 36.3 (1999): n. pag. Print.

Moran, Michael J, and Howard N Shapiro. *Fundamentals of Engineering Thermodynamics*. 4th ed. New York: John Wiley & Sons, 2000. Print.

Ng, P, PS V Lee, and JC H Goh. “Prosthetic Sockets Fabrication Using Rapid Prototyping Technology.” *Rapid Prototyping Journal* 8.1 (2002): 53-59. Print.

Oberg, Erik. *Machinery's Handbook*. Ed. Franklin Jones, Holbrook Horton, and Henry Ryffel. 27th. Rev. ed. New York: Industrial Press, 2008. PDF file.

Össur. "Icecast® Anatomy and Icecast® Compact." *Össur Prosthetics*. Össur, n.d. Web. 1 Dec. 2009.

Otto, Kevin, and Kristin Wood. *Product Design: Techniques in Reverse Engineering and New Product Development*. Upper Saddle River, New Jersey: Prentice Hall, 2001. Print.

Otto Bock. “Otto Bock - Harmony e-pulse.” *Otto Bock Harmony*. N.p., 2009. Web. 2 Nov. 2009. <http://www.ottobock.com////_com_en/.xsl/ .html?css=print&id=teaser2>.

Rapid Prototyping for Baghdad. “Selective Laser Sintering.” *Rapid Prototyping for Baghdad*. N.p., n.d. Web. 2 Nov. 2009. <http://www.rp4baghdad.org/.php?tech=2>.

Rogers, B, et at., 2007, “Advanced Trans-Tibial Socket Fabrication Using Selective Laser Sintering,” IEEE Neural Systems Rehabilitation Engineering, 14(3), pp. 304-310.

Rovick, Joshua S, and Dudley S Childress. “Additive Fabrication Technique for the CAM of Prosthetic Sockets.” *Rehabilitation Research and Development Progress Reports* 1994 (1994): 1-2. Print.

Smith, Douglas G. “Special Challenges in Outcome Studies for Amputation Surgery and Prosthetic Rehabiliation.” *Journal of Prosthetics and Orthotics* 18.1S (2006): 116-118. *American Academy of Orthotists and Prosthetis*. Web. 2 Nov. 2009. <http://www.oandp.org///_01s_116.asp>.

Stevens, Sean. “Design of a Compliant Prosthetic Socket Fabricated Using Selective Laser Sintering.” MS thesis. U of Texas at Austin, 1999. *Microsoft Word* file.

Street, G M. “Vacuum Suspension and its Effects on the Limb.” *Orthropädie-Technik* (Apr. 2007): 1-4. Web. 2 Nov. 2009. <http://www.ottobock.com////_com_en/_646d277_gb_vacuum_suspension.pdf>.

Vaughan, Meagan. “Design and Analysis of a Volume Adjustable Transtibial Prosthetic Socket for Pediatric Amputees in Developing Countries.” MS thesis. U of Texas at Austin, 1999. *Microsoft Word* file.

Williams, JD and Deckard, CR, 1998, “Advances in Modeling the Effects of Selected Parameters on the SLS Process,” Rapid Prototyping Journal, 4(2), pp. 90-100.

Zachariah, Santosh G, et al. “Shape and Volume Change in the Transtibial Residuum Over the Short Term: Preliminary Investigation of Six Subjects.” *Journal of Rehabilitation Research & Development* 41.5 (2004): 683-694. *JRRD*. Web. 2 Nov. 2009. <doi: 10.1682/.2003.10.0153>.

VITA

John Montgomery was born in Lafayette, Indiana, only a few miles from the college to which he would eventually return. He and his family moved to Alabama shortly after. After graduating from Homewood High School, he was admitted to Purdue University in West Lafayette, Indiana. His studies focused on mechanical design and control systems. Graduating in 2007 with a Bachelor's of Science degree in Mechanical Engineering, he chose to continue his education and pursue a Master's degree. That same year, he began working for Dr. Richard Crawford in the design area of the Mechanical Engineering school at the University of Texas at Austin. His research interests include mechanical design and modeling.

Permanent address: 326 S. Ingram St.
Pulaski, TN 38478

This thesis was typed by the author.